

Volume I of III (Pages A-1 through A-1382)

04-1323, -1487

**United States Court of Appeals
For the Federal Circuit**

ARTHROCARE CORPORATION,

*Plaintiff/Counterclaim Defendant-
Appellee,*

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

*Defendant/Counterclaimant-
Appellant.*

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE IN 01-CV-504,
CHIEF JUDGE SUE L. ROBINSON

NON-CONFIDENTIAL JOINT APPENDIX

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CONFIDENTIAL MATERIAL OMITTED FROM
THE NON-CONFIDENTIAL JOINT APPENDIX

The material omitted from the Non-Confidential Joint Appendix relates to confidential agreements executed by ArthroCare Corporation, documents filed under seal with the district court, and Smith & Nephew, Inc.'s counterclaim, the dissemination of which the district court has restricted.



(40)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

C.A. No. 01-504 SLR

STIPULATED PROTECTIVE ORDER

Pursuant to Federal Rule of Civil Procedure 26, and it appearing that discovery in the above-entitled action is likely to involve the disclosure of confidential information, and good cause appearing,

IT IS HEREBY ORDERED as follows:

1. Scope of Order. All documents, materials, items, testimony, or information, regardless of whether stored in electronic or paper form, that contain or comprise any trade secret or other confidential or proprietary technical, development, business, financial, or commercial information filed with the Court or produced either by a party or by a non-party in connection with this action shall be governed by this Protective Order. The terms of this Protective Order shall apply to all manner and means of discovery, including entry onto land or premises and inspection of books, records, documents and tangible things.

2. Confidential Information. Any documents, materials, items, testimony, or information filed with the Court or produced by any party or non-party as part of discovery in this action may be designated by such party or non-party as "Confidential Information." As a general guideline, materials designated "Confidential Information" shall be those things that may

be disclosed to the parties for the purposes of this litigation, but which must be protected from disclosure to non-parties as set forth herein.

3. Highly Confidential - Attorneys Eyes Only Information. Certain documents, materials, items, testimony, or information may be designated by a party or non-party as "Highly Confidential - Attorneys Eyes Only Information." The "Highly Confidential - Attorneys Eyes Only Information" designation shall be limited to such documents, materials, items, testimony, or information that the Designating Party believes, in good faith, contain information, the disclosure or intentional or inadvertent misuse of which is highly likely to cause significant harm to the business or competitive position of the Designating Party. Documents, materials, items, testimony, or information designated "Highly Confidential - Attorneys Eyes Only Information" may be disclosed only to the persons who have previously qualified to receive such information under the provisions of Paragraph 8 of this Protective Order, and may not be disclosed to any person currently prosecuting patent applications in the field of electrosurgical medical devices. Moreover, any person to whom documents, materials, items, testimony, or information designated "Highly Confidential - Attorneys Eyes Only Information" under this order is disclosed is hereby prohibited from drafting, preparing, or prosecuting patent applications concerning electrosurgical medical devices, or managing or supervising any such work, for the duration of this litigation including all appeals and one year thereafter.

4. Designated Information. "Designated Information" refers to "Confidential Information" and "Highly Confidential - Attorneys Eyes Only Information" including copies, extracts, or derivations therefrom, compilations and summaries thereof, and the information therein.

5. Designating Party. "Designating Party" refers to the Party or third party designating any material as "Confidential Information" or "Highly Confidential-Attorneys Eyes Only Information" under this Protective Order.

6. Use of Designated Information. Absent a specific order by this Court, Designated Information shall be used by the persons or entities to whom such information is disclosed solely for purposes of this action, and not for any other action or for any business, patent prosecution, licensing, competitive, or governmental purpose or function, and such information shall not be disclosed to anyone except as provided in this Protective Order.

7. Third Party Documents. Where a discovery request, subpoena, or deposition question calls for otherwise discoverable information that is held by the party to whom it is directed under obligations of confidentiality owed to another, the party to whom the discovery request, subpoena, or deposition question is directed shall promptly, and in all events within ten (10) court days of receipt of the discovery request calling for such disclosure except where the discovery request has been served prior to the date this order was approved by the Court, in which case within ten (10) court days after the date this order was approved by the Court:

(a) Identify to the party seeking the information the name and address of each person or entity whose confidentiality interests are implicated by the discovery request, subpoena or deposition question, and

(b) Seek consent to produce the requested information from each such person whose confidentiality interests are implicated. The request for consent shall be made in good faith, shall include a copy of this protective order, and the party seeking the discovery shall be copied on all correspondence constituting the request for consent.

(c) If the third party does not consent within ten (10) calendar days of the original service of the discovery request, subpoena, or deposition in question, the party seeking the discovery may move to compel production in addition to any other relief they may have.

8. Disclosure of Highly Confidential - Attorneys Eyes Only Information. Documents, materials, items, testimony, or information designated "Highly Confidential - Attorneys Eyes Only Information" pursuant to this Protective Order, or copies, derivations, or extracts therefrom, compilations and summaries thereof, and the information therein, may be

disclosed, given, shown, made available to, or communicated in any way only to the following persons:

(a) outside counsel of record for the parties in this action, and persons employed by said counsel who are working solely in secretarial, clerical, and paralegal capacities and who are assisting those attorneys in this action, except that any attorney currently involved in drafting, preparing, or prosecuting patent applications concerning electrosurgical medical devices, or managing or supervising any such work, shall not have access to "Highly Confidential - Attorneys Eyes Only Information";

(b) qualified court reporters, videographers and other similar persons making a stenographic, video or other record of testimony involving such documents, materials, items, testimony, or information and necessary clerical personnel thereof;

(c)(i) non-party consultants or testifying experts and their staffs in the preparation, trial or appeal of this action provided that they previously have been cleared by the parties pursuant to Paragraph 10 of this Protective Order, and (ii) jury or trial consultants and mock jurors, who are engaged to assist in the trial or preparation of this action, upon completion of the requirements set forth in Paragraph 11 of this Protective Order;

(d) the Court and the Court's staff;

(e) Smith & Nephew in-house attorney Joel Petrow, and persons working solely in secretarial, clerical, and paralegal capacities and who are assisting him in this action;

(f) current employees, officers and directors of the Designating Party;

(g) any person to whom the Designating Party agrees in writing.

However, in addition to satisfying the other requirements for access to "Highly Confidential-Attorneys Only Information" set forth in this order, the persons identified in subsections (c)(except for mock jurors), (e) and (g) of this Paragraph shall not be permitted access to materials or information designated "Highly Confidential - Attorneys Eyes Only Information" unless and until they sign a written Acknowledgment Pursuant to Protective Order

in the form attached hereto as Exhibit A that they have read this Protective Order, agree to be bound by its terms, and consent to jurisdiction in this Court, and mock jurors identified in (c)(ii) of this Paragraph shall not be permitted access to materials or information designated "Highly Confidential - Attorneys Eyes Only Information" unless and until they sign a written Agreement to Protect Confidential Information in the form attached hereto as Exhibit B. Outside counsel of record shall retain copies of all executed Acknowledgments and Agreements, and copies of all executed Acknowledgments shall be provided to the Designating Party.

9. Disclosure of Confidential Information. Documents, materials, items, testimony, or information designated "Confidential Information" pursuant to this Protective Order, or copies, derivations, or extracts therefrom, compilations and summaries thereof, and the information therein, may be disclosed, given, shown, made available to, or communicated in any way only to the following persons:

- (a) all persons set forth in Paragraph 8 above;
- (b) up to five regular employees of the party receiving Confidential Information who have a need to know the Confidential Information for purposes of this action; and
- (c) any person to whom the Designating Party agrees in writing.

However, the persons identified in subsections (b) and (c) of this Paragraph shall not be permitted access to materials or information designated "Confidential Information" unless and until they sign a written Acknowledgment Pursuant to Protective Order in the form attached hereto as Exhibit A that they have read this Protective Order, agree to be bound by its terms, and consent to jurisdiction in this Court. Outside counsel of record shall retain copies of all executed Acknowledgments, and copies of all executed Acknowledgments shall be provided to the Designating Party.

10. Clearance Procedure. The procedure for providing Designated Information to the persons described in Paragraph 8(c)(i) shall be as follows:

A. The party seeking to disclose such information shall, before any such disclosure, provide by facsimile and regular first class mail to each Designating Party:

1. The name of the person;
2. The present employer and title of the person;
3. A signed, written acknowledgment in the form of the Acknowledgment Pursuant to Protective Order attached hereto as Exhibit A by the person that he/she has read this Protective Order and agrees to be bound by its terms; and
4. A current resume or curriculum vitae and a list of all clients, and a general business description of each, for which the person has worked or consulted during the last four years, which shall be kept by the Designating Party on an attorneys' eyes only basis.

B. Within ten (10) calendar days after receipt of the information and written acknowledgment in the form of the Acknowledgment Pursuant to Protective Order attached hereto as Exhibit A described above, a party may object to the disclosure of Designated Information to the proposed recipient by serving a written objection by fax and mail, if the facts available to the objecting party give it reason to believe that there is a reasonable likelihood that the person may use the Designated Information for purposes other than the preparation for trial of this case. The parties shall meet and confer to try to resolve the objection. If the parties are unable to do so, the objecting party shall file a motion by letter brief, unless otherwise directed by the Court, to be heard telephonically on the earliest date available, unless otherwise ordered by the Court, seeking an order that disclosure of the Designated Information to the person not be permitted. Such motions must be filed and served by fax within twenty (20) calendar days of service of the party's written objection; otherwise, the objection is deemed waived. The burden of proof shall be with the objecting party.

C. During (a) the ten (10) calendar day period for objections, (b) the twenty (20) calendar day period for filing a motion if an objection is made, and (c) if a motion is brought, the period of time any such motion is pending, no disclosure of Designated Information shall be made to the person to whom the party seeking disclosure seeks to disclose the Designated Information.

11. Jury or Trial Consultants and Mock Jurors. Jury or trial consultants, including graphics consultants used in any phase of the case, and their staffs who are engaged to assist in the trial or preparation of this action may have access to Designated Information, provided that any such persons shall first sign a written acknowledgement in the form of the Acknowledgment Pursuant to Protective Order attached hereto as Exhibit A that they have read this Protective Order, agree to be bound by its terms, and consent to jurisdiction in this Court. Outside counsel of record shall retain copies of all such executed acknowledgements until final termination of this action. Mock jurors and focus group members who are hired by such consultants in preparation for trial of this action may have access to Designated Information, provided that any such person shall first sign a written acknowledgment in the form of the Agreement to Protect Confidential Information attached hereto as Exhibit B. Such executed Acknowledgments and Agreements shall be retained under the control of counsel until final termination of this action. No documents, materials, items, testimony, or information embodying Designated Information shall be left in the possession of any such person.

12. Procedure for Designating Materials. Any party or non-party wishing to invoke the provisions of this Protective Order shall designate the documents, materials, items, testimony, or information, or portions thereof, which he, she, or it considers confidential at the time such information is disclosed, or as soon thereafter as the person or entity seeking protection becomes aware of the nature of the information or materials disclosed and sought to be protected. With respect to documents, the items produced must be marked or stamped (a) "Confidential" pursuant to Paragraph 2 or (b) "Highly Confidential - Attorneys Eyes Only,"

"Attorney's Eyes Only - Highly Confidential," or "Confidential - Outside Attorneys Eyes Only" pursuant to Paragraph 3 on all pages by the producing party or non-party. In the case of information stored on electronic media, the items produced shall be clearly marked or stamped on the media if possible or, if not possible, shall be designated in a writing accompanying the production of the item. With respect to deposition testimony, the witness under deposition, or his, her, or its counsel, and/or any counsel representing any party or non-party at the deposition, shall invoke the provisions of this Protective Order during the course of the deposition, giving adequate warning to counsel for the party or non-party that testimony about to be given is deemed confidential, and shall instruct the Court Reporter to mark the cover of the transcript with the appropriate confidentiality legend. The failure to so designate the testimony on the record at the deposition may be corrected pursuant to Paragraph 17 of this order. The provisions of this Paragraph may be invoked by counsel for a witness with respect to the witness's entire deposition, or any portion thereof, at any time during the deposition, provided, however, that the attorney has a good faith belief that the information is confidential and that the attorney promptly and in good faith responds to requests that the transcript or portions thereof be de-designated or re-designated pursuant to paragraph 18.

13. Filing Under Seal. Any Designated Information that is included with, or the contents of which are disclosed in any way in any pleading, motion, deposition transcript, or other papers filed with the Clerk of the Court, shall be filed in sealed envelopes prominently marked with the notation:

CONFIDENTIAL INFORMATION

(or HIGHLY CONFIDENTIAL - ATTORNEYS EYES ONLY INFORMATION)

SUBJECT TO PROTECTIVE ORDER

ArturoCare v. Smith & Nephew, Civ. A. No. 01-504 SLR

THIS ENVELOPE IS NOT TO BE OPENED NOR THE CONTENTS

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OR BY AGREEMENT OF THE PARTIES

14. Treatment of Designated Information. All Designated Information under this Protective Order shall be kept only by those permitted access herein, and in such a manner as to protect against disclosure to those not permitted access to such Designated Information. Copies of Designated Information may only be made where reasonably necessary to prepare work product or conduct proceedings in this litigation.

15. Limitations on Protective Order. Any individual, such as a deposition witness, trial witness, or potential witness who is a third party or former employee of the Designating Party may be shown (but may not keep) Designated Information by an attorney bound by this Protective Order provided that the individual is identified on the face of the document as a signatory, author, addressee, or recipient of such Designated Information or (i) the individual is a former employee of the Designating Party and (ii) the outside attorney has a reasonable, good faith belief that, although not identified on the face of the document, the individual generated, read, or reviewed the Designated Information while employed by the Designating Party, and the individual signs the Acknowledgment Pursuant to Protective Order in the form attached hereto as Exhibit A. A party may use its own Designated Information to examine or cross-examine any trial or deposition witness. In no circumstances will the use of Designated Information during a deposition or at trial constitute a waiver of the designated status of the materials.

16. Improper Designation. A party or non-party providing documents, materials, items, testimony, or information that inadvertently fails to properly designate such documents, materials, items, testimony, or information or who inadvertently mis-designates such documents, materials, items, testimony, or information pursuant to this Protective Order at the time of the production may re-designate such documents, materials, items, testimony, or information in order to correct its failure. Such correction and notice thereof shall be made in writing, accompanied by substitute copies of each item, appropriately designated. The party receiving the substitute copies shall make its best efforts to promptly return or destroy the previous

unmarked or mis-marked documents, materials, items, testimony, or information and all copies thereof.

17. Designation of Depositions. Counsel attending a deposition who does not designate any portion of the transcript pursuant to this Protective Order on the record at the deposition shall have ten (10) calendar days after receipt of the official deposition transcript from the court reporter in which to correct his or her failure. Such correction shall be made in writing to the reporter, with copies to all other counsel, designating the portion(s) of the transcript that contain Confidential or Highly Confidential - Attorneys Eyes Only information, and directing the reporter to mark that portion of the transcript accordingly. Prior to and during the pendency of the ten (10) calendar day period, all deposition transcripts shall be treated as if designated in their entirety as Highly Confidential - Attorneys Eyes Only.

18. Objection to Designation. If at any time during the pendency or trial of this action, any party claims that information is not appropriately designated, the objecting party may serve a written notice of objection on all parties and other affected persons, identifying with particularity the items as to which the designation is challenged, stating the basis for each challenge, and proposing a new designation for each item. Within ten (10) calendar days of receiving such notice, the Designating Party shall respond in writing served by facsimile, and either agree to the new designation proposed by the objecting party or explain why the designation should not be changed. If the Designating Party and the objecting party cannot resolve the dispute in informal meet and confer discussions, the objecting party may move for an order from the Court for re-designation. The Designating Party shall have the burden to justify the original designation.

19. Improper Disclosure. If Designated Information is disclosed to any person other than in the manner authorized by this Order, the person responsible for the disclosure must immediately bring all pertinent facts relating to such disclosure to the attention of counsel for the Designating Party and, without prejudice to any other rights and remedies of the parties, make its

best effort to prevent further disclosure by it or by the person who was the recipient of such information and to recover or retrieve any such information improperly disclosed.

20. Inadvertent Production of Privileged Materials. Counsel shall make their best efforts to identify materials protected by the attorney-client privilege or the work product doctrine prior to the disclosure of any such materials. The inadvertent production of any document or thing shall be without prejudice to any claim that such material is protected by the attorney-client privilege or protected from discovery as work product, and no producing party shall be held to have waived any privilege by virtue of inadvertent production. If a producing party discovers that materials protected by the attorney-client privilege or work product doctrine have been inadvertently produced, counsel for the producing party shall promptly give notice to counsel for the receiving party. The receiving party shall take prompt steps to ensure that all known copies of such material are returned to the producing party. The receiving party may afterward contest such claims of privilege or work product as if the materials had not been produced, but shall not assert that a waiver occurred as a result of the production.

21. Inadmissibility of Designation Status. Unless the parties stipulate otherwise, evidence of the existence or nonexistence of a designation under this Protective Order shall not be admissible for any purpose, nor shall the designation or acceptance of any information designated pursuant to this Protective Order constitute an admission or acknowledgment that the material so designated is in fact proprietary, confidential, or a trade secret.

22. Disposal of Designated Information. Upon termination of this action, settlement, or final judgment including exhaustion of all appeals, the originals and all copies of Designated Information shall be either destroyed or turned over to the party or non-party who produced such Designated Information, or to their respective counsel, within sixty (60) calendar days. However, outside counsel for the parties may retain a complete copy of all pleadings, transcripts, exhibits and correspondence for archival purposes. If Designated Information is destroyed

pursuant to this Paragraph, counsel shall provide to opposing counsel a certificate of destruction identifying when and how the destruction was performed within the same sixty (60) day period.

23. Disclosure to Management. The Parties understand and agree that it may be necessary to disclose certain Designated Information to senior management of the opposing party from time to time, for purposes of assessing the case and its merits, considering settlement, and the like. The Parties hereby agree to cooperate in good faith in considering all such reasonable requests, e.g., on an item by item basis, to permit such limited disclosures. All such disclosures shall be subject to the terms of this Protective Order, and the persons receiving such disclosures shall be subject to the terms of Paragraph 8(g) and/or 9(c) as appropriate, including the requirement to sign an acknowledgement in the form of the Acknowledgment to Pursuant to Protective Order attached hereto as Exhibit A.

24. Termination. The terms of this Protective Order shall survive termination of this action.

25. Modification. This Protective Order is being entered without prejudice to the right of any party or other person to move the Court for modification of or relief from any of its terms.

Dated: February 28, 2002

MORRIS, NICHOLS, ARSHT & TUNNELL FISH & RICHARDSON P.C.

By: Jack B. Blumenfeld
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Attorneys for Defendant
SMITH & NEPHEW, INC.

SO ORDERED this 4th day of March, 2002.

John L. Johnson
United States District Judge

EXHIBIT A
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

C.A. No. 01-504 SLR

ACKNOWLEDGMENT PURSUANT TO PROTECTIVE ORDER

JOEL PETROW hereby states as follows:
[Name of Recipient]

I have been furnished with a copy of the STIPULATED PROTECTIVE ORDER entered in this action which I have read and understood; and I agree to be bound by the terms of said STIPULATED PROTECTIVE ORDER and hereby subject myself to the jurisdiction of the United States District Court for the District of Delaware for purposes of enforcing that Order and this Acknowledgment.

Dated: 7 MAR 02

Name: Joel Petrow

EXHIBIT B

AGREEMENT TO PROTECT CONFIDENTIAL INFORMATION

1. This Agreement is between _____
[Consultant]
and _____ residing at _____
[Name]
2. I understand that I will receive information that is confidential and is not to be disclosed to anyone (including my family members) outside the research group that I am participating in today.
3. I agree not to disclose any information I learn today or to use such information outside the research group I am participating in today.

Signed: _____
Name: _____
Date: _____

A 752

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

MEMORANDUM ORDER

At Wilmington this 9th day of April, 2003, having heard oral argument and having reviewed papers submitted in connection therewith;

IT IS ORDERED that the disputed claim language in United States Patent Nos. 5,697,536; 5,697,882; and 6,224,592, as identified by the above referenced parties, shall be construed as follows, consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit:¹

¹The court notes that claim construction is not final until judgment is entered. The parties apparently developed their claim construction with a focus on obtaining summary judgment of infringement or invalidity. If, on a more developed record, the court finds the current claim construction to be in error, the claims will be re-construed accordingly.

04/10/03

1. "Connector."

The court shall apply the ordinary definition of the word "connector." The word connect means "to bind or fasten together; join or unite; link[.]"² The word "connector," in terms of the '536 patent, shall be construed to mean "a structure that electrically links the electrode terminal to the high frequency power supply."

2. "Electrically Conducting Fluid Supply."

Consistent with the prosecution history, the phrase "electrically conducting fluid supply" shall be construed to mean "a medical container that stores electrically conducting fluid." (D.I. 267, Ex. 10 at 4-5) An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline. (Id.)

4. "Spacing a Return Electrode Away From the Body Structure" and "the Return Electrode is Not in Contact with the Body Structure."

The claim limitation "the return electrode is not in contact with the body structure" is clear - the return electrode is not to contact the body at all during the performance of the claimed method.

²The Random House College Dictionary, 285 (revised ed. 1980).

5. "Electrically Conducting Fluid" and "Electrically Conductive Fluid."

Consistent with the ordinary definition, "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current." Examples of electrically conducting fluids are blood and saline.

6. "Directing or Delivering the Electrically Conductive Fluid to the Target Site."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

7. "Electrode Terminal."

Consistent with the intrinsic evidence of the patents in suit, "electrode terminal" means "one or more active electrodes."

8. "Active Electrode."

The court shall apply the ordinary definition of the term "active electrode" in the relevant art. The term "active electrode" means "a stimulating electrode . . . applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density."³

³The New IEEE Standard Dictionary of Electrical and Electronics Terms, 13 (5th ed. 1993).

9. "Return Electrode."

As contrasted with an active electrode, the term "return electrode" means "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."⁴

10. "Insulating Member."

The court shall apply the ordinary definition of the phrase "insulating member." Thus, the phrase "insulating member" shall be construed to mean "a member which provides a high degree of resistance to the passage of charge."

11. "500 to 1400 Volts Peak to Peak."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

12. "Through the Region of the Target Site."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

13. "Immersing."

The court shall apply the ordinary definition of the term "immersing." The term "immersing" shall be construed to mean "to plunge into or place under a fluid[.]"⁵

⁴The court notes that the area of contact in the present invention contacts the electrically conductive fluid. In the prior art, the area of contact contacted the body.

⁵The Random House College Dictionary, 664 (revised ed. 1980).

14. "Electrosurgical System."

The court shall apply the ordinary definition of the term "system." The term "system" shall be construed to mean "an assemblage or combination of things or parts forming a unitary whole[.]""

15. "Distal End" and "Proximal End."

The court shall apply the ordinary definition of the terms "distal" and "proximal." The term "distal end" shall be construed to mean "the end situated away from the point of origin or attachment." The term "proximal end" shall be construed to mean "the end situated toward the point of origin or attachment."


United States District Judge

⁶The Random House College Dictionary, 1335 (revised ed. 1980).

⁷See The Random House College Dictionary, 385 (revised ed. 1980).

⁸See The Random House College Dictionary, 1066 (revised ed. 1980).

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

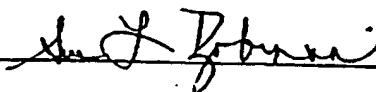
ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

JUDGMENT IN A CIVIL CASE

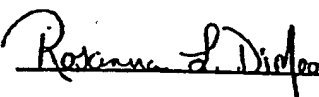
ArthroCare Corporation, plaintiff, and Smith & Nephew, defendant, came before the Court for a trial by jury. On May 12, 2003, the jury rendered a verdict (D.I. 405, copy attached) on the issues of patent infringement of claims 46, 47, and 56 of the '536 patent, claims 13, 17, and 54 of the '882 patent, claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent and of patent invalidity of claims 46, 47, and 56 of the '536 patent, claims 13, 17, and 54 of the '882 patent, and claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent and of patent enablement of claims 13, 17, and 54 of the '882 patent and of patent validity of the Certificate of Correction of claim 1 of the '882 patent. The jury found for plaintiff as to all issues.

Therefore,

IT IS ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of ArthroCare Corporation, plaintiff, and against Smith & Nephew, defendant.


United States District Judge

Dated: June 20, 2003


(By) Deputy Clerk

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

Jack B. Blumenfeld, Esquire, Karen Jacobs Loudon, Esquire and James W. Parrett, Jr., Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Matthew D. Powers, Esquire, Jared Bobrow, Esquire and Perry Clark, Esquire of Weil, Gotshal & Manges LLP, Redwood Shores, California.

William J. Marsden, Jr., Esquire and Keith A. Walter, Jr., Esquire of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Mark J. Hebert, Esquire and Kurtis D. MacFerrin, Esquire of Fish & Richardson P.C., Boston, Massachusetts.

MEMORANDUM OPINION

Dated: March 10, 2004
Wilmington, Delaware


ROBINSON, Chief Judge

I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent") directed to electrosurgery devices and methods. (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (D.I. 10) Smith & Nephew also asserted counterclaims for declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended their answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219) Specifically, Smith & Nephew alleges that Arthrocare and Ethicon, Inc. violated antitrust law by bringing and maintaining the instant action to restrain trade "knowing the '536, '882, and/or '592 patents are invalid,

unenforceable, and/or not infringed by any act of Smith & Nephew." (D.I. 219 at ¶27-37)

ArthroCare is organized under the laws of the State of Delaware with its principal place of business in California. (D.I. 1 at ¶2) Smith & Nephew is also organized under the laws of State of Delaware with its principal place of business in Massachusetts. (D.I. 1 at ¶3) Smith & Nephew manufactures and sells the following three allegedly infringing products: the Saphyre bipolar ablation probe ("Saphyre"), the Dyonics Control RF System ("Control RF"), and the ElectroBlade Resector ("ElectroBlade"). The court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201(a).

The court separated the issues raised by the parties into two phases pursuant to Smith & Nephew's motion to bifurcate the issues of willfulness and damages until a jury verdict on infringement and validity of the patents in suit. (See D.I. 206) The first phase, in turn, included the issues of infringement, validity, and inequitable conduct ("the patent litigation"). The parties tried these issues before a jury from April 30, 2003 through May 9, 2003. On May 12, 2003, the jury returned a verdict in favor of Arthrocare on all issues. (See D.I. 405) That is, the jury found that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of the following claims of the three patents in suit with its Saphyre,

ElectroBlade, and Control RF products: claims 46, 47, and 56 of the '536 patent, claims 13, 17, and 54 of the '882 patent, and claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent. (See id.) The jury also found that none of the patents were invalid on anticipation or lack of enablement grounds. (See id.)

The second phase is presently pending before the court and includes the issues of willfulness, damages, and Smith & Nephew's antitrust counterclaims. Currently before the court is Arthrocare's motion to dismiss Smith & Nephew's antitrust counterclaims.¹ (D.I. 429) For the reasons that follow, the court grants said motion.

II. BACKGROUND

Arthrocare filed suit against Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. in the Northern District of California on February 13, 1998, alleging infringement of eight claims in four patents. (Arthrocare Corp. v. Ethicon, Inc., No. C-98-0609 WHO (N.D. Cal. Dec. 1, 1998); D.I. 321, ex. A at 1) The claims at issue included: (1) claims 40 and 44 of United States Patent No. 5,697,909 ("the '909 patent"); (2) claim 45 of

¹Arthrocare filed this motion to dismiss on May 27, 2003. Smith & Nephew has not responded, despite mentioning its antitrust counterclaims in its answering brief opposing Arthrocare's motion for a permanent injunction in the patent litigation filed with the court on June 4, 2003. (See D.I. 436) The court, therefore, presumes that Smith & Nephew does not oppose the motion.

the '536 patent; (3) claim 101 of United States Patent No. 5,697, 281 ("the '281 patent); and (4) claims 1, 26, 28, and 32 of the '882 patent. (Id. at 2) On March 10, 1998, Arthrocare moved for a preliminary injunction against Ethicon and Mitek to enjoin the two from making, using, importing, selling, or offering for sale an electrosurgery system marketed and sold under the VAPR System name. (Id.) Senior Judge William H. Orrick issued a memorandum decision on December 1, 1998 denying Arthrocare's preliminary injunction motion. (Id. at 33) Judge Orrick found that the defendants raised substantial questions as to (1) whether claims 40 and 44 of the '909 patent and claims 26 and 28 of the '882 patent are invalid for obviousness; (2) whether claim 45 of the '536 patent and claim 101 of the '281 patent are invalid for anticipation and obviousness; and (3) whether claims 1 and 32 of the '882 patent are invalid for lack of enablement. (Id.) The parties settled the litigation in June 1999 prior to trial.

III. STANDARD OF REVIEW

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a court to dismiss a complaint for failure to state a claim upon which relief can be granted. The purpose of a motion to dismiss is to test the sufficiency of a complaint, not to resolve disputed facts or decide the merits of the case. Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993). In analyzing a motion to dismiss under this rule, the court, therefore, must

accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiff. See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998). The court, however, is not required to credit "bald assertions" or "legal conclusions." Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint; and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. The defendant has the burden of persuasion to show that no claim has been stated. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991).

IV. DISCUSSION

Smith & Nephew's antitrust counterclaims are premised on the idea that Arthrocure and Ethicon filed "sham" litigation against Smith & Nephew to prevent or to restrain it from entering the arthroscopic surgery market.² Smith & Nephew appears to base this allegation on Judge Orrick's ruling that there were substantial questions concerning the validity of the '882 and '536 patents. In fact, Smith & Nephew particularly asserts that

²Arthrocure and Ethicon have a combined seventy-five percent share of the market in the United States for arthroscopic surgical devices. (D.I. 219 at ¶35)

the "patent infringement action is objectively baseless in that no reasonable litigant could realistically expect success on the merits." (D.I. 219 at ¶36) Arthrocare argues in rebuttal that the jury's verdict in its favor on infringement and invalidity proves that the patent litigation was not a "sham."

A party who petitions the government for redress generally is immune from antitrust liability. Eastern R.R. Presidents Conference v. Noerr Motor Freight, 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965). Commonly referred to as the Noerr-Pennington doctrine, this immunity extends to persons who petition all types of government entities, including legislatures, administrative agencies, and courts. California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972). Although originally developed in the antitrust context, courts have applied this doctrine universally to business torts. See Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 128-29 (3d Cir. 1999) (applying the doctrine to common law claims of malicious prosecution, tortious interference with contract, tortious interference with prospective economic advantage, and unfair competition); see also IGEN Int'l, Inc. v. Roche Diagnostics GmbH, 335 F.3d 303, 310 (4th Cir. 2003). Noerr-Pennington immunity, however, is subject to an exception for "sham" litigation. The Supreme Court has held that Noerr-Pennington immunity does not apply to petitions that are a

"mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Noerr, 365 U.S. at 144. In this regard, the Supreme Court outlined a two-part definition for the term "sham litigation." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49 (1993). As an objective first part, "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. at 60. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, then the suit does not qualify as sham litigation and is immunized under the Noerr-Pennington doctrine. Id. In other words, the antitrust claim premised on the sham exception must fail. The subjective second part of the definition arises only if the challenged litigation is objectively meritless. In such case, the court must decide whether the "baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" Id. at 60-1.

The court disagrees with Smith & Nephew and finds that Arthrocare instituted the patent litigation in a legitimate attempt to protect its patented inventions. The court rejects the notion that Judge Orrick's decision undermined Arthrocare's belief that its patents were valid, enforceable, and infringed by Smith & Nephew's Saphyre, ElectroBlade, and Control RF probes.

Judge Orrick's opinion was based upon a partially developed record and was issued in response to Arthrocare's motion for a preliminary injunction. Under 35 U.S.C. § 282, a patent is presumed valid, and invalidity may be established only by clear and convincing evidence. See 35 U.S.C. § 282 (2003). Such is not the standard employed in a preliminary injunction proceeding.

Additionally, the court notes that in Applera Corp. v. Micromass UK Ltd., 204 F. Supp.2d 724, 782 (D. Del. 2002), antitrust counterclaims like those at bar were dismissed after a jury verdict of infringement and validity, based upon the reasoning that a jury verdict in plaintiff's favor proved the litigation had merit. Applying this reasoning to the instant case, the court likewise concludes that the objective threshold for "sham" litigation is not satisfied and that the Noerr-Pennington doctrine shields Arthrocare from liability for Smith & Nephew's antitrust counterclaims. Accordingly, the court grants Arthrocare's motion to dismiss Smith & Nephew's counterclaims.

V. CONCLUSION

For the reasons stated, the court grants Arthrocare's motions to dismiss Smith & Nephew's antitrust counterclaims. An order shall issue.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

O R D E R

At Wilmington, this 10th day of March, 2004, consistent with
the memorandum opinion issued this same day;

IT IS ORDERED that Arthrocare's motion to dismiss Smith &
Nephew's antitrust counterclaims is granted. (D.I. 429)


United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

Jack B. Blumenfeld, Esquire, Karen Jacobs Loudon, Esquire and James W. Parrett, Jr., Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Matthew D. Powers, Esquire, Jared Bobrow, Esquire and Perry Clark, Esquire of Weil, Gotshal & Manges LLP, Redwood Shores, California.

William J. Marsden, Jr., Esquire and Keith A. Walter, Jr., Esquire of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Mark J. Hebert, Esquire and Kurtis D. MacFerrin, Esquire of Fish & Richardson P.C., Boston, Massachusetts.

MEMORANDUM OPINION

Dated: March 10, 2004
Wilmington, Delaware


ROBINSON, Chief Judge

I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful direct, contributory, and inducing infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent"). (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (*Id.*) Smith & Nephew also asserted counterclaims for a declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended their answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219)

ArthroCare is organized under the laws of the State of Delaware with its principal place of business in California. (D.I. 1 at ¶2) Smith & Nephew is also organized under the laws of State of Delaware with its principal place of business in

Massachusetts. (Id. at 13) The court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

The court separated the issues raised by the parties into two phases, the first phase to include the issues of infringement, validity, and inequitable conduct and the second phase to include the issues of damages, willfulness, and antitrust counterclaims. From April 30, 2003 through May 9, 2003, the parties tried the issues of infringement and invalidity before a jury. The court ruled on May 12, 2003 that the parties could submit their inequitable conduct cases on the briefs limited to the record created at trial. (See D.I. 418 at 1071-02) Currently before the court are the parties' post-trial motions on the issues of infringement, invalidity, and inequitable conduct.¹ (D.I. 424, 427, 432, 437, 455, 458)

¹Smith & Nephew challenges every decision made by the jury in rendering its verdict and numerous evidentiary decisions rendered by the court during the trial.

Smith & Nephew filed a motion to modify the protective order to permit key Smith & Nephew business personnel to view specific terms of Arthrocare's settlement agreement with Ethicon in an attempt to facilitate settlement discussions between the parties. (D.I. 432) Because there are no active settlement discussions currently ongoing, the court denies this motion as moot.

Smith & Nephew also filed a motion for judgment as a matter of law on the issues of (1) infringement under the doctrine of equivalents; (2) infringement of claim 54 of the '882 patent by non-suction models of the Saphyre probe; and (3) direct infringement of the '592 and '882 patents. (See D.I. 459 at 5, 6, and 19) None of these issues were presented to the jury. Likewise, neither the jury instructions nor the special verdict form asked the jury to decide these issues. Accordingly, the court finds that judgment as a matter of law is improper under the federal rules and will not entertain these motions.

II. BACKGROUND

A. Electrosurgery In General

The patents in suit generally relate to electrosurgery and to surgical devices and methods that employ high frequency voltage to cut and ablate tissue. These devices are of either a monopolar or a bipolar nature. A monopolar device, as the name suggests, consists of only a single electrode. It directs an electric current from the exposed or active electrode through a patient's body to a return electrode externally attached to the patient's body. In contrast, a bipolar device consists of two electrodes. An active electrode in contact with the patient's tissue transmits an electric current through the patient's tissue to a return electrode also in contact with the patient's tissue. When using either type of device, the target region must be treated with isotonic saline to maintain an isotonic environment around the tissue and to keep the area in clear view.

Electrosurgical techniques are advantageous because they reduce patient bleeding and the trauma associated with operations involving cutting. At the same time, a diverse range of risks may be implicated. With monopolar devices, electric current may flow in undefined paths through a patient's body. Also, high voltages typically must be applied to generate a current suitable for cutting or ablation using either monopolar or bipolar

devices. Such high voltage may damage or destroy surrounding tissue.

B. The Patents In Suit

The patents in suit involve improvements over the monopolar and bipolar devices of the prior art. Specifically, the '536 patent claims an electrosurgical system comprising an electrosurgical probe, a return electrode, and a fluid delivery element. The '592 and '882 patents, in turn, claim methods of using the system disclosed in the '536 patent to apply electrical energy adjacent to the target tissue without submerging the target tissue in an electrically conducting irrigant. Each patent will be considered in further detail as relevant to the parties' post-trial motions.

1. The '536 Patent

The '536 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 18, 1996. The '536 patent traces priority to the now abandoned U.S. Application No. 817,575. It was granted with sixty-four claims on December 16, 1997. On December 23, 1999, a third party filed a request for an ex parte reexamination based solely upon prior art. The United States Patent and Trademark Office ("PTO") granted this request

and, after reexam, issued a "Notice of Intent to Issue an Ex Parte Reexamination Certificate" as to all original claims.

Claims 46, 47, and 56 are presently asserted and are apparatus type claims. Claims 46 and 56 depend from claim 45. Claim 47 depends from claim 46. These claims read as follows:

45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:
a high frequency power supply;
an electrosurgical probe comprising a shaft having a proximal end and a distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;
a return electrode electrically coupled to the electrosurgical power supply; and
an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.
46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.
47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.
56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

('536 patent, col. 18 at ll. 13-36; col. 19 at ll. 11-15)

The court construed disputed terms of the '536 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The term "electrosurgical system" shall be given its "ordinary definition" and construed to mean "an assemblage or combination of things or parts forming a unitary whole."
2. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."
3. The term "connector" shall be construed to mean "a structure that electrically links the electrode terminal to the high frequency power supply."
4. The phrases "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" shall be construed to mean that the return electrode is not to contact the body at all during the performance of the claimed method.²
5. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

²The court supplemented this construction in its jury instructions with the following addition: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

2. The '882 Patent

The '882 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 22, 1995 and traces priority to the same original application as the '536 patent, namely U.S. Application No. 817,575. The '882 patent was granted with fifty-six claims on December 16, 1997. Claims 13, 17, and 54 are presently asserted. All are method type claims. Claims 13 and 17 depend from claim 1 and claim 54 depends from both claim 1 and claim 28. These claims recite:

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode, electrically coupled to a high frequency voltage source;
positioning the active electrode in close proximity to the target site in the presence of an electrically conducting fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.
13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.
17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.
28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, col. 24 at ll. 5-18; 54-56, 64-65; col. 25 at ll. 38-51; col. 28 at ll. 9-10)

Pursuant to multiple certificates of correction granted after the '882 patent originally issued, the language recited in several claims was corrected. Of interest to the parties' post-trial motions, claim 1 was corrected on April 7, 1998. Claim 54 was corrected on May 2, 1998. For sake of clarity, the corrected language is shown below in bold with the original language in parentheses.

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode **terminal** in close proximity to the target site in the presence of an electrically conducting [terminal] fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode,

the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer:

54. The method of claims [1 and 28] 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, Certificates of Correction dated August 25, 1998, April 7, 1998, and May 2, 2001) (emphasis added)

3. The '592 Patent

The '592 patent, entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," was issued on May 1, 2001 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on July 27, 1998 and traces priority to the '882 patent. Specifically, the '592 patent is a division of U.S. Patent No. 5,871,469, which is a division of the '882 patent. The '592 patent was granted with forty-three claims on May 1, 2001. Claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 are presently asserted and are all method type claims. Claims 3, 4, 11, and 21 depend from claim 1. Claim 26, 27, 32, and 42 depend from claim 23. These claims read as follows:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:
 - positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;
 - positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate

a current flow path between the electrode terminal and the return electrode; and
applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

3. The method of claim 1 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.
4. The method of claim 1 further comprising delivering the electrically conductive fluid to the target site.
11. The method of claim 1 wherein the electrically conductive fluid comprises isotonic saline.
21. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.
23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:
contacting an active electrode with the body structure in the presence of an electrically conductive fluid;
spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and
applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.
26. The method of claim 23 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path

between the active electrode and the return electrode.

27. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.
32. The method of claim 23 wherein the electrically conductive fluid comprises isotonic saline.
42. The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

('592 patent, col. 24 at ll. 6-21; 36-32; 64-65; col. 25 at ll. 36-37, 43-54, 61-67; col. 26 at ll. 20-21, 59-60)

The court construed disputed terms of the '592 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The phrase "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" means that the return electrode is not to contact the body at all during the performance of the claimed method.³
2. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."
3. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."

³The court supplemented this construction in its jury instructions. The court added the following: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

(D.I. 353)

C. The Accused Products

Smith & Nephew presently manufactures and sells the Saphyre bipolar ablation probe ("Saphyre") and the ElectroBlade Resector ("ElectroBlade") for use in arthroscopic procedures. These products entered the market in 2002. It also previously manufactured and sold the Dyonics Control RF System ("Control RF") for use in arthroscopic procedures, but discontinued this product from the market in early 2002. (D.I. 436 at 3)

The Saphyre product consists of a stainless steel shaft with a plastic handle and a single large area active electrode at the far or "distal" end of the "shaft." (D.I. 400 at 3) The inner and outer surfaces of the Saphyre shaft are covered with an insulating coating, except at the distal tip where the active electrode is located. (Id.) A single return electrode clip is attached on top of this insulated shaft. (Id.) The return electrode and insulated shaft are covered with another insulating layer, except for a window located over the return electrode clip near the distal end of the shaft. (Id.) The Saphyre probe is connected to the Smith & Nephew Vulcan Generator. (Id. at 4)

The ElectroBlade probe consists of a stainless steel inner tube (i.e., inner blade) and a hollow stainless steel shaft (i.e., outer blade). (Id.) The inner blade slides into the shaft hollow and includes an opening near its distal end. The

inner blade rotates within the shaft when connected to a motor drive unit. (Id.) When it passes the edge of the opening in the shaft during rotation, a shearing action results. (Id. at 5)

This shearing action serves to resect, or cut, target tissue. In addition to resecting tissue, the inner blade also acts as the active electrode when coagulation power is applied to the probe.

(Id.) The return electrode is another hollow, stainless steel tube that runs from a point close to the opening in the shaft to a point in the handle. (Id.) The return electrode is covered with an insulating layer, except for an exposed section near the distal end of the shaft. The ElectroBlade probe does not contain a fluid delivery system. Instead, a separate instrument delivers fluid to the target tissue during an arthroscopic procedure.

(Id. at 4) The ElectroBlade probe is connected to the Valleylab Force FX Generator. (Id. at 5)

Before being discontinued, the Control RF probe consisted of a stainless steel shaft in a plastic handle with a single active electrode at the far end. (Id. at 6) A return electrode was located near the active electrode at the far end of the shaft. The majority of the shaft was covered with an insulating material, except in the region of the active and return electrodes. (Id.) The Control RF probe did not contain a fluid delivery system; instead, a separate instrument pumped fluid during an arthroscopic surgery to the target tissue. (Id.) The

Control RF probe was connected to a Valleylab Force FX Generator via a Dyonics Control RF Generator Adaptor. (Id.)

D. The Alleged Prior Art

Throughout the course of the trial, Smith & Nephew introduced numerous documents in an attempt to establish that the patents in suit were invalid in light of prior art references.⁴ These references include four patents and two journal articles as follows: (1) U.S. Patent No. 4,116,198 (the "'198 patent"); (2) U.S. Patent No. 4,381,007 (the "'007 patent"); (3) U.S. Patent No. 4,674,499 (the "'499 patent"); (4) U.S. Patent No. 5,122,138 (the "'138 patent"); (5) "Vaporization of Atherosclerotic Plaques by Spark Erosion," 5 Journal of the American College of Cardiology, No. 6 at 1382-6 (1985) written by Cornelis J. Slager, et. al. (the "Slager article"); and (6) "Uber ein Instrument zur leckstromfreien transurethralen Resektion," (translated as "An Instrument for Transurethral Resection Without Leakage of Currents"), 24 Acta Medico Technica, No. 4 at 129-134 (1976) written by Von E. Elsasser and Eberhard. Roos (the "Elsasser/Roos article"). The '007 and '499 patents were cited to the PTO during the prosecution of the '536 and '882 patents. (See '536 patent cover; '882 patent cover) The Elsasser/Roos article was also cited during the prosecution of the '536 patent, and the

⁴The parties did not dispute that the documents introduced at trial by Smith & Nephew qualified as prior art in that they were available prior to the filing dates of the patents in suit.

'198 patent was cited during the reexamination of the '536 patent. (See '198 patent cover; '198 patent reexamination certificate)

The '198 patent, entitled "Electro-Surgical Device," is the most contentious item of prior art raised in the litigation at bar. Eberhard Roos is named as the sole inventor on this patent. In general, it relates to a bipolar electrosurgical device that may be passed through an endoscope. The device consists of a treatment electrode, a neutral electrode, a cable means to connect the treatment electrode to one pole of a high-frequency generator, another means for connecting the neutral electrode to the other pole of the high-frequency generator, and a channel for directing washing liquid to the treatment site. ('198 patent, col. 7 at ll. 45-61) The '198 invention is particularly directed toward electrosurgical operations on the filled bladder. (Id., col. 1 at ll. 18-21) Claim 1 of this patent recites:

1. In combination, an endoscope having an endoscope body of substantially tubular shape, an electrosurgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being

formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.

(Id., col. 7 at ll. 45-62) (emphasis added)

The '007 patent is entitled, "Multipolar Corneal-Shaping Electrode with Flexible Removable Skirt," and names James D. Doss as the sole inventor. This patent is directed toward a multipolar probe that employs radiofrequency electrical current to heat and thereby induce reshaping of the cornea in mammals. ('007 patent, col. 1 at ll. 10-13) The probe employs a plurality of electrode means that may be connected to the terminal of a radio-frequency source. (Id., col. 6 at ll. 60-61)

The '499 patent is entitled, "Coaxial Bipolar Probe," and names David S.C. Pao as the sole inventor. It discloses an electrosurgical bipolar electrode probe for use in ophthalmic, electrocautery, and electrocoagulation operations. ('499 patent, col. 1 at ll. 15-18)

The '138 patent is entitled, "Tissue Vaporizing Accessory and Method for an Endoscope," and names Kim H. Manwaring as the sole inventor. This patent is directed toward radio frequency energized endoscopic tissue dissection, vaporization, and coagulation devices designed for use in conjunction with an endoscope. ('138 patent, col. 1 at ll. 7-9; col. 2 at ll. 5-8) These devices may utilize a monopolar RF generator.

The Elsasser/Roos article essentially describes using one of the bipolar electrosurgery devices described in the '198 patent in thirty-two surgeries. In the summary section, this article states that "[t]he high-frequency current . . . flows directly from the active cutting electrode, through the tissue to be cut and the irrigation liquid, to the annular neutral electrode at the proximal end of the resectoscope shaft." (DTX 59-B at 7) (emphasis added) The Slager article describes the in vitro vaporization of fibrous and lipid plaques from segments of atherosclerotic human aortas using an electrical spark generator. (DTX 65)

E. The Arthrocare Corp. v. Ethicon, Inc. Decision

Arthrocare filed suit against Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. in the Northern District of California on February 13, 1998, alleging infringement of eight claims in four patents. (Arthrocare Corp. v. Ethicon, Inc., No. C-98-0609 WHO (N.D. Cal. Dec. 1, 1998); D.I. 321, ex. A at 1) The claims at issue included: (1) claims 40 and 44 of U.S. Patent No. 5,697,909 (the "'909 patent"); (2) claim 45 of the '536 patent; (3) claim 101 of U.S. Patent No. 5,697, 281 (the "'281 patent"); and (4) claims 1, 26, 28, and 32 of the '882 patent. (Id. at 2) The case was assigned to Senior Judge William H. Orrick.

On March 10, 1998, Arthrocare moved for a preliminary injunction against Ethicon and Mitek to enjoin the two from making, using, importing, selling, or offering for sale an electrosurgery system marketed and sold under the VAPR System name. (Id.) Judge Orrick issued a memorandum decision on December 1, 1998 denying Arthrocare's preliminary injunction motion. (Id. at 33) Judge Orrick found substantial questions as to whether: (1) claims 40 and 44 of the '909 patent and claims 26 and 28 of the '882 patent are invalid for obviousness in light of the '198 patent and Elsasser/Roos article; (2) claim 45 of the '536 patent and claim 101 of the '281 patent are invalid for anticipation and obviousness in light of the '198 patent and Elsasser/Roos article; and (3) claims 1 and 32 of the '882 patent are invalid for lack of enablement. (Id.) The parties settled the litigation in June 1999 prior to trial.

F. Procedural History

In March 2003, the parties filed multiple motions for partial summary judgment. The court heard oral argument regarding these motions on April 1, 2003 and issued a memorandum opinion and order on April 9, 2003. (D.I. 352) The court denied Arthrocare's motions for partial summary judgment of infringement of the asserted claims of the '882 patent and claim 1 of the '592 patent, denied Smith & Nephew's motion for summary judgment of noninfringement of the asserted claims of the '882, '592, and

'536 patents, denied Arthrocare's motion for partial summary judgment that the patents in suit are not invalid due to obviousness based on an on-sale bar or public use, denied Smith & Nephew's motion for summary judgment of invalidity based upon prior art, and denied Smith & Nephew's motion for partial summary judgment of nonenablement, indefiniteness, and lack of written description. (Id.)

During the April 1, 2003 oral argument, the court also heard the parties' positions with respect to the disputed claim language of the patents in suit in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). The court issued a claim construction memorandum order on April 9, 2003. (D.I. 353)

G. The Trial

On April 30, 2003 through May 12, 2003, the parties tried their claims to a jury. The jury found by a preponderance of the evidence that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of claims 46, 47, and 56 of the '536 patent with its Saphyre, ElectroBlade, and Control RF products. (D.I. 405) The jury also found by clear and convincing evidence that the certificate of correction for claim 1 of the '882 patent was not invalid and by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 13, 17, and 54 of the

'882 patent with its Saphyre, Saphyre with Suction, and Control RF products. (Id.) In addition, the jury found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent with its Saphyre, ElectroBlade, and Control RF products.⁵ (Id.) The jury further found that Smith & Nephew did not prove by clear and convincing evidence that the patents in suit are invalid due to anticipation or that claims 13, 17, and 54 of the '882 patent are invalid for lack of enablement. (Id.) The court entered final judgment on June 20, 2003 based upon the jury's verdict. (D.I. 452)

III. STANDARD OF REVIEW

A. Motion for Judgment as a Matter of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial under Federal Rule of Civil Procedure 50(b), the moving party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings." Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)

⁵The jury was not asked to decide whether Smith & Nephew contributed to the infringement or induced the infringement of claims 21 and 42 of the '592 patent with its Saphyre or ElectroBlade products.

(quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." Id. In summary, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

B. Motion for a New Trial

The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. See Allied Chem. Corp. v. Daiflon, Inc., 449 U.S. 33, 36 (1980).

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

New trial are commonly granted in the following situations: (1) where the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) where newly-discovered evidence surfaces that would likely alter the outcome of the trial; (3) where improper conduct by an attorney or the court unfairly influenced the verdict; or (4) where the jury's verdict was facially inconsistent. See Zarow-Smith v. N.J. Transit Rail Operations, 953 F. Supp. 581, 584 (D. N.J. 1997) (citations omitted). The court, however, must proceed cautiously and not substitute its own judgment of the facts and assessment of the witnesses' credibility for the jury's independent evaluation. Nevertheless,

[w]here a trial is long and complicated and deals with a subject matter not lying within the ordinary knowledge of jurors a verdict should be scrutinized more closely by the trial judge than is necessary where the litigation deals with material which is familiar and simple, the evidence relating to ordinary commercial practices. An example of subject matter unfamiliar to a layman would be a case requiring a jury to pass upon the nature of an alleged newly discovered organic compound in an infringement action.

Lind v. Schenley Indus. Inc., 278 F.2d 79, 90-91 (3d Cir. 1960).

IV. DISCUSSION

A. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Direct Infringement Grounds⁶

1. The Legal Standard for Direct Infringement

A patent is directly infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a) (2002). A court should employ a two-step analysis in making a direct infringement determination. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. See id. Construction of the claims is a question of law subject to de novo review. See Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). The trier of fact must then compare the properly construed claims with the accused infringing product. See id. This second step is a question of fact. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). Direct infringement occurs where each limitation of

⁶When motioning the court for a new trial under Fed. R. Civ. P. 59, Smith & Nephew appears to also move for a new trial under Fed. R. Civ. P. 50(b). Smith & Nephew premises this motion on the same grounds raised in its motion for judgment as a matter of law under Fed. R. Civ. P. 50(b). (See D.I. 456 at 33-34). The court, therefore, shall consider its Rule 50(b) motion for judgment as a matter of law as including an alternative motion for a new trial.

at least one claim of the patent is found exactly in the alleged infringer's product. See Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987). The patent owner has the burden of proving direct infringement and must meet its burden by a preponderance of the evidence. See SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

2. The '536 Patent

Smith & Nephew renews its motion for judgment as a matter of law that its accused products cannot directly infringe independent claim 45 or dependent claims 46, 47, or 56 of the '536 patent because the probes covered by the '536 patent must deliver fluid to the target site in light of the court's claim construction for the term "electrosurgical system." Smith & Nephew asserts that the probes used in its Saphyre, Control RF, and ElectroBlade products do not introduce such a fluid supply, even though they are used in the presence of electrically conducting fluid. To this end, Smith & Nephew explains that fluid is introduced to the target site by a separate piece of medical equipment like an IV bag or an Intelijet pump and that the separate equipment is not part of the "electrosurgical system." (D.I. 415 at 976, 1014) Smith & Nephew alleges that Arthrocare's expert, Dr. Nahum Goldberg, improperly ignored the requirement that an electrically conducting fluid supply be part

of the claimed system in his testimony at trial. (See D.I. 411 at 398-99) Accordingly, Smith & Nephew maintains that its products fall outside the scope of the asserted claims in the '536 patent.

The court disagrees. A jury reasonably may have discounted all testimony presented by Smith & Nephew with respect to direct infringement of the '536 patent after finding Smith & Nephew's use of the term "electrosurgical system" inconsistent with the court's claim construction. The court construed this term to mean "an assemblage or combination of things or parts forming a unitary whole." The court did not require that all elements physically interconnect as implied by Smith & Nephew. Following the court's construction, the jury likely understood that fluid may be delivered from any source (e.g., the probe itself, an IV bag, or an Intelijet pump) and still permit formation of an "electrosurgical system."

Additionally, there is ample evidence in the record upon which a jury reasonably could have concluded that the accused products meet all limitations of the asserted claims. Dr. Goldberg testified that the accused devices will only function in the presence of electrically conducting fluid. (See id. at 398-99, 405, 412) Smith & Nephew's own expert, Dr. Kenneth Taylor, also testified that the accused devices require, and will not work without, electrically conducting fluid. (See D.I. 416 at

1453-54) Dr. Taylor likewise admitted that a probe is not required to deliver fluid for the probe and fluid supply to be considered an "electrosurgical system." (See id. at 1413-16) Moreover, Dr. Taylor explained the components described in the Slager reference comprised an electrosurgical system, even though fluid was not delivered through the probe. (See id. at 1414)

Besides direct witness testimony, the jury viewed multiple video clips of the accused products in operation during "normal procedure." (See PX 105, DTX 315, DTX 316, DTX 897) In all clips, the target sites were submerged under saline fluid. (Id.) The jury further saw product literature from Smith & Nephew, namely the ElectroBlade "Instruction for Use" guide, which described the use of the ElectroBlade in conjunction with the Intelijet pump and referred to this assembly as the "Recommended System Configuration." (PX 189 at 3) On the basis of this evidence, a reasonable jury could conclude that the Saphyre, Control RF, and ElectroBlade probes form an "electrosurgical system" as required by the '536 claims and, as such, infringe the '536 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '536 patent is not infringed by the accused products.

Concerning a new trial, the verdict is not against the weight of the evidence and no miscarriage of justice will result if the jury's verdict stands. Smith & Nephew did not present

evidence that so overwhelmingly favors its position that the jury clearly erred in finding that the accused products directly infringe the '536 patent. In addition, the court finds that none of the other reasons for granting a new trial, such as the discovery of new evidence or improper attorney conduct, exist under the facts at bar. Thus, the court denies Smith & Nephew's motion for a new trial as to literal infringement of the '536 patent.

B. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, Based Upon the Validity of the Certificate of Correction for the '882 Patent

Smith & Nephew argues that its Saphyre, ElectroBlade, and Control RF probes would not directly infringe the '882 patent but for the certificate of correction that broadened the number of electrodes recited in application claim 23, which became patent claim 1, from four electrodes (i.e., an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal) to two electrodes (i.e., an electrode terminal and a return electrode). In other words, Smith & Nephew does not contest that its Saphyre, Control RF, and ElectroBlade products directly infringe the asserted claims of the '882 patent as corrected by the certificate of correction because its accused probes have only two electrodes as recited by the corrected

claims.' (See D.I. 415 at 1110-1112) Rather, Smith & Nephew argues that the certificate of correction is invalid. In this regard, Smith & Nephew asserts that it was not obtained to correct a mistake, but only to broaden the claims to advance its lawsuit against Ethicon. Additionally, Smith & Nephew argues that, even if the certificate was filed to correct obvious errors, it was not manifest how such corrections should have been made.

The court disagrees. The record is replete with evidence upon which a jury reasonably could have found that the certificate of correction was validly made to correct legitimate errors in the claims.. Congress enabled a patent applicant to correct errors in a patent due to the applicant's mistake in 35 U.S.C. § 255. This section provides:

Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

⁷Smith & Nephew contends that its accused products, however, do not infringe the original claims of the '882 patent. (See also D.I. at 1110)

35 U.S.C. § 255 (2000). This section enumerates two specific kinds of applicant error which may be corrected through a certificate of correction: (1) errors of a clerical or typographical nature; and (2) errors of a minor character. The Federal Circuit has noted that the words of § 255 do not preclude broadening corrections. Superior Fireplace Co. v. The Majestic Prods. Co., 270 F.3d 1358, 1371 (Fed. Cir. 2001). However, the Federal Circuit opined that "a broadening correction of a clerical or typographical error [may] be allowed only where it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected." Id. at 1373. With regard to mistakes of a minor character, the Federal Circuit has interpreted the language of § 255 to exclude mistakes that broaden a claim. Id. at 1374. The Federal Circuit further has held that the clear and convincing standard is applicable to challenges to the validity of a certificate of correction. Id. at 1367.

Applying these principles to the facts at bar, the court notes that Mr. John Raffle, Arthrocare's in-house counsel, filed an amendment on March 25, 1997 prior to the '882 patent grant to change the phrase "active electrode" to "electrode terminal." Mr. Raffle testified that he attempted to make this change for every occurrence of the phrase "active electrode" in the claims. (See D.I. 417 at 1524-26) Mr. Raffle also testified that the

phrase "the active electrode" in uncorrected application claim 23 lacked antecedent basis because the precise words "an active electrode" did not appear earlier in the claim set. (See id. at 1515-16) Based upon this testimony, the jury could have inferred that Mr. Raffle inadvertently overlooked two occurrences of the phrase "active electrode" in his amendment and that reference to "the active electrode" after the phrase "an electrode terminal" was a typographical error. A jury likewise reasonably could have concluded that both the typographical error and the proper way to correct it were evident in light of the prosecution history of the '882 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the certificate of correction is invalid.

With respect to a new trial, the weight of the evidence does not warrant a new trial to avoid a miscarriage of justice. Arthrocare offered sufficient evidence upon which a jury could have found that the certificate of correction is valid. Hence, the court denies Smith & Nephew's motion for a new trial premised on the invalidity of the certificate of correction for the '882 patent.

C. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Contributory and Inducing Infringement Grounds

1. The Legal Standard for Contributory Infringement

The doctrine of contributory infringement is codified at 35

U.S.C. § 271(c):

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

The Federal Circuit has explained that this form of infringement is premised on the idea that a defendant who displays sufficient culpability should be held liable as an infringer, even though he did not technically make, use, or sell a patented invention.

Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990). The Federal Circuit also has noted that "[s]uch liability was under a theory of joint tortfeasance, wherein one who intentionally caused, or aided and abetted, the commission of a tort by another was jointly and severally liable with the primary tortfeasor." Id. Based upon the language of § 271(c), there can be no contributory infringement in the absence of direct infringement. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341-42 (1961). In addition,

there can be no contributory infringement without knowledge that the component made or sold was especially adapted for a particular use proscribed by a known patent. See Hewlett-Packard Co., 909 F.2d at 1469. Actual intent to cause or contribute to infringement is not necessary to establish contributory infringement. Id. Instead, "[a] seller of a 'material part' of a patented item may be a contributory infringer if he makes a non-staple article that he knows was 'especially made or especially adapted for use in an infringement of such patent.'" Husky Injection Molding Sys. v. R&D Tool & Eng'g Co., 291 F.3d 780, 784 (Fed. Cir. 2002) (citing 35 U.S.C. § 271(c); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 219 (1980)). Furthermore, the "occasional and aberrant use of these products, [even] where they are clearly designed to be used in a system specified in the claims of a patent, does not rise to the level of 'a staple article or commodity of commerce suitable for substantial non-infringing use.'" Preemption Devices v. Minnesota Mining & Mfg. Co., 630 F. Supp. 463, 471 (E.D. Pa. 1985) (citing Dennison Mfg. Co. v. Ben Clements & Sons, Inc., 467 F. Supp. 391, 428 (S.D.N.Y. 1979)).

2. The Legal Standard for Inducing Infringement

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." As with contributory infringement, direct infringement is a

prerequisite to inducing infringement. Met-Coil Sys. Corp. v. Korner Unlimited, Inc., 803 F.2d 684, 687 (Fed. Cir. 1986). Additionally, the alleged infringer must have knowingly induced infringement. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990) (citing Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)). The Federal Circuit has stated that "although section 271(b) does not use the word 'knowing, the case law and legislative history uniformly assert such a requirement." Water Techs., 850 F.2d at 668. In this regard, mere knowledge of the acts alleged to constitute inducement is not enough. Manville Sales Corp., 917 F.2d at 553. Rather, the plaintiff has the burden of showing that "the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." Id.

3. The Direct Infringement Prerequisite for Contributory and Inducing Infringement⁹

Considering the direct infringement prerequisite for the acts of contributory and inducing infringement, Smith & Nephew

⁹Smith & Nephew argues that it is not liable for contributory or inducing infringement because its accused products do not directly infringe the '536 patent. The court shall not consider this argument in the instant analysis because a jury found that Smith & Nephew directly infringed the '536 patent and the court herein denied Smith & Nephew's motion for judgment as a matter of law on direct infringement grounds for this patent. See supra, Section IV, 1, A.

Recall also Smith & Nephew did not argue noninfringement of the '882 patent as corrected by the certificate of correction.

argues that the Saphyre, Control RF, and ElectroBlade probes do not practice the limitations of asserted claims of the '592 patent. Specifically, Smith & Nephew contends that the return electrodes on its products frequently contact target tissue during the performance of the method for applying electrical energy recited in claims 1 and 23 of the '592 patent.⁹ Claim 1 requires "positioning a return electrode . . . such that [it] is not in contact with the body structure," and claim 23 requires "spacing a return electrode away from the body structure." ('592 patent, col. 24 at ll. 13-14; col. 25 at ll. 48) Smith & Nephew alleges that Dr. Goldberg improperly applied a temporal limitation in testifying that the "only way not to infringe this claim with the device is to make sure that the return electrode . . . is always in contact when the energy is on." (D.I. 411 at 421-22) (emphasis added) Smith & Nephew particularly notes that the return electrodes on its products contact tissue while the probe is being positioned before energy is applied (i.e., during the second step enumerated in claims 1 and 23). Smith & Nephew, therefore, advocates that a reasonable jury could not find that

⁹Procedurally, Smith & Nephew raised the issue of direct infringement of the '592 patent in a motion for judgment as a matter of law. As the court previously noted above, this issue was not presented to the jury. See *supra*, Introduction, n. 1. The court, therefore, construes Smith & Nephew's argument in the context of its motion for judgment as a matter of law on both contributory and inducing infringement grounds.

the use of any of its accused products satisfies the return electrode "not in contact/spaced away" limitations given this contact time. (See D.I. 354 at 7)

Viewing the record in a light most favorable to Arthocare as the non-moving party, the court disagrees with Smith & Nephew's argument. The record reflects that there are times when the return electrode is not in contact with target tissue and all of the other claim limitations are performed, thereby supporting the jury verdict of literal infringement. To this end, Smith & Nephew's expert, Dr. Michael Choti, admitted that when the active electrode on the Control RF probe is positioned near the target site and energy is applied, the return electrode does not always contact tissue. (See D.I. 412 at 743-744) Ms. Karen Drucker, the ElectroBlade project manager, and Ms. Kate Knudsens, the Saphyre project manager, similarly acknowledged that video clips of the accused products in operation show times when the return electrodes of the ElectroBlade and Saphyre probes, respectively, were not in contact with tissue while energy was applied. (See D.I. 415 at 1036, 985) Mr. Warren Heim, Smith & Nephew's consultant, also testified that the Control RF probe was designed so that the return electrode would not contact tissue during use. (See D.I. 414 at 957-58) Additionally, Mr. Joe McCreary, the Saphyre marketing manager, testified that the Saphyre can function even if the return electrode is not in contact with

tissue. (See D.I. 412 at 555) Moreover, the Saphyre Sales Guide warns that "care should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft." (PX 390 at 37)

The ElectroBlade Sales Training CD likewise instructs users to "ensure that the entire tip including the return electrode is immersed in saline, to "present" the active electrode to the tissue, and "to use suction to pull bleeding tissue to the blade for coagulation." (PX 199 at 11, 7) The Control RF

"Instructions for Use" further informs doctors to be sure that the active and return electrodes are "completely surrounded" by electrically conducting fluid during use." (PTX 205 at 1)

Considering the totality of this evidence, a jury reasonably could have found that Smith & Nephew's accused products meet the "not in contact/spaced away" limitations of the asserted claims and thereby directly infringe the '592 patent.

4. Contributory Infringement

Smith & Nephew asserts that its products have "substantial non-infringing uses" such that they were not designed to infringe the asserted claims of the patents in suit. Specifically, Smith & Nephew claims that these non-infringing uses include: (1) operation of the probes to apply energy while the return electrode touches tissue (i.e., noninfringement of the '592 patent); (2) operation of the probes to apply energy without creating a vapor layer, thereby achieving coagulation instead of

ablation (i.e., noninfringement of the '882 patent); and (3) operation of the probes as part of an "electrosurgical system" that does not have a fluid supply (i.e., noninfringement of the '536 patent).

The court is again unpersuaded by these arguments. The evidence of record for the '592 patent discussed above shows that the Saphyre, ElectroBlade, and Control RF probes were constructed to prevent the return electrode from contacting tissue. The court finds that similar evidence exists with respect to the '882 and '536 patents. In particular, Smith & Nephew refers to its Saphyre product line as "ablation" probes in its sales guides. (See PX 381 at 1, PX 390 at 10). Smith & Nephew also markets its Saphyre and Control RF probes for use in ablation, not coagulation, even though both may provide coagulation. (See PX 390 at 4, PX 593 at 11, 29, PX 205 at 1) Additionally, several witnesses at trial testified that the Saphyre, ElectroBlade, and Control RF probes must be used with electrically conducting fluid. (See D.I. 411 at 397-98, 405, 412; D.I. 414 at 848; D.I. 415 at 1013) More specifically, Mr. Sparks and Ms. Drucker testified that electrically conducting fluid must be delivered to the target site in arthroscopic surgery. (See D.I. at 814-16; D.I. 415 at 1013-14) A reasonable juror, taking all of this evidence into account, could have concluded that the accused probes were designed to infringe and that the occasional or

aberrant use of one of them in a non-infringing manner, as suggested by Smith & Nephew, does not constitute a substantial noninfringing use. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for contributing to the infringement of the patents in suit.

As to a new trial, none of the reasons for granting a new trial exists in the instant case. That is, the jury's verdict is not against the weight of the evidence. Rather, both sides presented evidence to support their respective positions. Additionally, no miscarriage of justice will result by upholding the jury's verdict. For these reasons, the court denies Smith & Nephew's motion for a new trial on contributory infringement grounds.

5. Inducing Infringement

Smith & Nephew argues that it is not liable as an inducing infringer because Arthrocare failed to prove that Smith & Nephew intends to cause its customers to infringe the asserted claims of the patents in suit. The court finds that Smith & Nephew's arguments are not well founded and that sufficient evidence exists in the record to support the jury's verdict of inducing infringement. In particular, Ms. Knudsen and Mr. Heim testified that they read the patents in suit before the Saphyre probe design was complete and prior to design efforts commenced for the ElectroBlade and Control RF probes. (D.I. 415 at 991; D.I. 414.

at 936-37, PX 735 at 23-25) They further stated that they evaluated Arthrocare's patented products prior to designing the accused products. (D.I. 414 at 951, D.I. 415 at 977-78) On this basis, a jury reasonably could have found that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit when using the Saphyre, ElectroBlade, and Control RF probes. Consequently, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for inducing infringement.

Regarding a new trial, the jury's verdict of inducing infringement is not against the clear weight of the evidence. Moreover, no miscarriage of justice will result if this verdict stands. Accordingly, the court concludes that a new trial is not warranted and denies Smith & Nephew's motion for a new trial on inducing infringement grounds.

D. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Invalidity Grounds

Smith & Nephew renewed its motion for judgment as a matter of law that the patents in suit are invalid based on prior art grounds. Before reaching the substance of this motion, Arthrocare challenges Smith & Nephew's right to raise this motion claiming that Smith & Nephew failed to preserve the issue of invalidity before the case was submitted to the jury pursuant to Fed. R. Civ. P. 50(a). Rule 50(b) permits consideration of such renewed

motions for judgment as a matter of law only when a motion for a directed verdict has been made at the close of the evidence offered by an opponent. In pertinent part, Rule 50(b) states:

If, for any reason, the court does not grant a motion for judgment as a matter of law made at the close of all the evidence, the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion. The movant may renew its request for judgment as a matter of law by filing a motion no later than 10 days after entry of judgment.

Rule 50(a) requires that "[a] motion for a directed verdict shall state the specific grounds therefor." This requirement is in place to afford the non-moving party with the opportunity to reopen its case and present additional evidence. See Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 814 (3d Cir. 1984) (citing Lowenstein v. Pepsi-Cola Bottling Co., 536 F.2d 9, 11 (3d Cir. 1976)).

In the case at bar, Smith & Nephew motioned for a directed verdict three times. It first made a Rule 50(a) motion at the close of Arthrocare's case. (See D.I. 415 at 1161) It made a second Rule 50(a) motion at the close of all the evidence. (See D.I. 417 at 1549) Smith & Nephew then renewed this motion prior to the jury charge. (See D.I. 418 at 1700) Since the issue of invalidity had not been presented when Smith & Nephew initially moved for a directed verdict, the court finds that Smith & Nephew's first motion was not directed to the invalidity of the patents in suit. The court notes, however, that the issue of

invalidity was in evidence at the time Smith & Nephew made its second and third motions. The court also notes that it indicated after these latter motions that Smith & Nephew's rights were reserved, despite the fact that Smith & Nephew did not specifically state the precise grounds for its motions. (See D.I. 417 at 1549; D.I. 418 at 1700). As well, the court did not require any argument concerning the motions when raised and precluded Smith & Nephew from discussing them. The court, therefore, concludes that it would be unjust to Smith & Nephew not to consider its renewed motion for judgment as a matter of law. Accordingly, the court will consider the instant motion.

1. The Legal Standard for Invalidity

A patent is presumed valid, and each claim whether in independent, dependent, or multiple dependent form is presumed to be valid independent of the validity of other claims. 35 U.S.C. § 282 (2003). The party asserting invalidity, consequently, has the burden of proof. Id. This burden is satisfied only by proving facts establishing invalidity by clear and convincing evidence. Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003) (citing Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1569 (Fed. Cir. 1996)). The patentee, therefore, need not submit any evidence to support the validity of a patent. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1570 (Fed.

Cir. 1986). Moreover, the challenger's burden is especially difficult to meet when the art relied on at trial was considered by the PTO. BOC Healthcare, Inc. v. Nellcor, Inc., 892 F. Supp. 598, 602 (D. Del. 1995). Indeed, the Federal Circuit has stated:

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984).

a. Invalidity on Anticipation Grounds

A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference explicitly discloses each and every limitation of the claimed invention. Lamar Marine, Inc. v. Baronet, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). The Federal Circuit has stated that "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991). In determining whether a patented invention is explicitly anticipated, the claims are read in the context of the patent specification in which they arise and in which the invention is described. Glaverbel Societe Anonyme v.

Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed. Cir. 1995). The prosecution history and the prior art may be consulted if needed to impart clarity or to avoid ambiguity in ascertaining whether the invention is novel or was previously known in the art. Id.

A prior art reference also may anticipate without explicitly disclosing a feature of the claimed invention if that missing characteristic is inherently present in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. Id. That is, "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. The Federal Circuit also has observed that "[i]nherency operates to anticipate entire inventions as well as single limitations within an invention." Schering Corp. V. Geneva Pharms. Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003). Moreover, recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. Id. at 1377.

An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. See Key Pharms. v. Hercon Labs Corp., 161 F.3d 709, 714

(Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art. Id. A finding of anticipation will invalidate the patent. Applied Med. Res. Corp. v. U.S. Surgical Corp., 147 F.3d 1374, 1378 (Fed. Cir. 1998)

i. The '536 Patent

Smith & Nephew charges that the '536 patent is anticipated by several prior art references. In particular, Smith & Nephew contends that the '499 patent, the '007 patent, the '198 patent, and the Elsasser/Roos article each disclose all of the limitations of the invention claimed in the '536 patent. As support for its anticipation argument, Smith & Nephew asserts that its expert Dr. Taylor testified that the '198, '499, and '007 patents and the Elsasser/Roos article individually disclose every limitation recited in claims 45, 46, and 56 of the '596 patent. (See D.I. 416 at 1294-1313) Smith & Nephew also contends that Arthocare did not offer any evidence to contradict or rebut this testimony, but instead cross-examined Dr. Taylor about select claim limitations to confuse and mislead the jury.

Viewing the record in a light most favorable to Arthocare as the verdict winner, the court is unpersuaded by Smith & Nephew's argument. The evidence presented at trial reasonably supports the jury's verdict of infringement. The PTO specifically considered the prior art effect of the '499 and '007 patents during the prosecution of the '536 patent and allowed the

asserted claims. The PTO also considered the '198 patent and the Elsasser/Roos article during the reexamination of the '536 patent and issued a notice of intent to issue reexamination certificate. (See D.I. 417 at 1537-1540) The court concludes that this evidence was sufficient to convince a jury of the validity of the '536 patent.

Additionally, Arthocare solicited testimony from Dr. Taylor establishing that each of the asserted references fails to disclose at least one limitation of the asserted claims. Dr. Taylor admitted on cross-examination that the '499 patent does not disclose a current flow path through electrically conducting fluid as required by the asserted '536 claims. Dr. Taylor testified that it instead discloses inserting the electrodes directly into the target tissue, thereby facilitating electrical current flow between the axial and outer electrodes through the tissue. (See D.I. 416 at 1409-12) Dr. Taylor also stated in his deposition that both electrodes disclosed in the '007 patent have substantially the same current density (i.e., meaning that the '007 patent did not disclose a return electrode), though asserted at trial that his deposition testimony was in error. (See id. at 1383-85) Dr. Taylor likewise testified that the '007 patent and the '198 patent do not disclose the location of a connector with respect to the proximal end of the shaft as required by the asserted claims. (See id. at 1400; 1371) Additionally, Dr.

Taylor testified that the Elsasser/Roos article fails to explicitly describe the function for the structure located at the proximal end of the disclosed probe. (See id. at 1298) Dr. Taylor further testified on cross-examination that neither the '198 patent nor the Elsasser/Roos article disclose the use of either saline or Ringer's lactate, both of which are electrically conducting fluids. (See id. at 1340-43) Dr. Taylor, in fact, stated that the references do not distinguish between the electrically non-conducting liquid used with monopolar devices and the liquid used in bipolar devices. (Id.) Moreover, Dr. Taylor stated that there would be no need for the steel band described in Figure 5 of the '198 patent if the liquid shown in Figure 5 was electrically conducting. (See id. at 1345) Given the totality of this evidence, a jury may have properly found that the prior art references do not anticipate the '536 invention. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that the asserted claims of the '536 patent are invalid on anticipation grounds.

With respect to a new trial, no miscarriage of justice will result if the jury's verdict of validity as to the '592 patent stands. Mindful not to substitute its own judgment of the facts and the credibility of the witnesses for those of the jury, the verdict is neither against the weight of the evidence nor facially inconsistent. Furthermore, since the conclusion of

trial, no new evidence has surfaced to alter the outcome of the trial. The court, consequently, denies Smith & Nephew's motion for a new trial on anticipation grounds for the '592 patent.

ii. The '882 Patent

Smith & Nephew contends that the '138 patent and the Slager article individually disclose each and every limitation recited in the asserted claims of the '882 patent. Smith & Nephew specifically argues that the '138 patent anticipates claims 1, 13, and 54 and that the Slager article anticipates claims 1, 13, 17, and 54. Smith & Nephew relies on the expert testimony of Dr. Taylor and Dr. Kim Manwaring for support. (See id. at 1313-1320; D.I. 414 at 886-96) As with the '536 patent discussed above, Smith & Nephew maintains that Arthocare failed to present rebuttal evidence to contradict the experts, but instead misleadingly cross-examined these experts regarding particular claim limitations to confuse the jury.

The court, nonetheless, finds that a reasonable jury could have concluded on the record before it that several differences exist between the '882 invention and the '138 patent and the Slager article such that Smith & Nephew failed to prove anticipation by clear and convincing evidence. Focusing first on the '138 patent, Dr. Manwaring admitted that this reference discloses a spark discharge followed by vaporization of the fluid. (See id. at 907-908) In contrast, claims 1, 13, 17, and

54 of the '882 patent disclose vaporization of the electrically conducting fluid followed by electrical discharge. Claim 13 also requires generation of photons having a wavelength in the ultraviolet spectrum. Dr. Manwaring stated at trial that the '138 patent does not explicitly mention ultraviolet photons and that he was unaware of any testing that established that the '138 device emits ultraviolet photons. (See id. at 897-98). Similarly, Dr. Taylor confirmed that he performed no testing to establish that a device built according to the '138 patent generates ultraviolet light. (See D.I. 416 at 1420-21) Finally, claim 54 of the '882 patent discloses evacuating the fluid beyond the vicinity of the target tissue. Both Dr. Manwaring and Dr. Taylor admitted that the '138 patent, in contrast, discloses drawing the fluid into the catheter tip where it remains in the vicinity of the target tissue. (See D.I. 414 at 904-05; D.I. 416 at 1432-33)

Turning to consider the Slager article, Dr. Taylor agreed that it does not disclose the application of energy to a "target site on a patient body structure" as required by the preamble of claims 1 and 28. Dr. Taylor instead testified that the Slager article discussed the application of energy to a tissue in a lab dish. (See id. at 1426-27) Since sufficient evidence exists for the jury to have concluded that the '138 patent and the Slager article do not disclose each and every limitation found in the

claims of the '882 patent, Smith & Nephew is not entitled to prevail on its motion for judgment as a matter of law. The court, consequently, denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on anticipation grounds.

Addressing Smith & Nephew's motion for a new trial on anticipation grounds, Smith & Nephew has failed to demonstrate that the verdict is against the weight of the evidence or that a new trial is necessary to remedy a miscarriage of justice. For these reasons, the court denies Smith & Nephew's motion for a new trial on anticipation grounds as to the '882 patent.

iii. The '592 Patent

Smith & Nephew asserts that the '007 patent and the Slager article each recite all the limitations of the asserted claims of the '592 patent. Smith & Nephew relies on Dr. Taylor's testimony to support this anticipation argument and, as with the '536 and '882 patents, again claims that Arthocare failed to elicit any rebuttal testimony. Rather, Smith & Nephew charges that Arthocare misleadingly cross-examined Dr. Taylor regarding certain claim limitations to cause confusion among the jurors:

Substantial evidence exists in the record to distinguish the '592 invention from the cited prior art references in support of the jury's verdict of validity. The '592 patent contains the same "return electrode" limitation as the '536 patent. As

discussed above in relation to the '536 patent, the '007 patent does not disclose a return electrode limitation. Additionally, the '007 patent fails to disclose the waveform necessary to determine whether it anticipates the 500 to 1,400 volts peak to peak recited in claim 21.¹⁰ Dr. Taylor admitted that when he opined that the '007 patent discloses a voltage in the range of 500 to 1,400 volts peak-to-peak, he presumed that the wave form was a sine wave since this is the most common form used. (See id. at 1401-1404) In light of this presumption, a jury reasonably may have dismissed Dr. Taylor's testimony concerning the anticipatory effect of the '007 patent on the '592 patent. As to the Slager article, claims 1 and 28 of '592 patent contain the same "on or within a patient's body" preamble language as claims 1 and 26 of '882 patent. The Slager article, on the other hand, only discloses the application of energy to tissue in a lab dish as noted above. Furthermore, claims 1 and 23 of the '592 patent specify that the return does not touch the body structure. Dr. Taylor testified that he was unable to determine the location

¹⁰The '007 patent discloses a 20 to 200 root-mean-square voltage. Presume that the wave form produced by the generator is a sine wave, the court acknowledges that this root-mean-square voltage range may be converted to a peak-to-peak voltage using a 2.83 conversion factor. Applying this factor to the voltage range disclosed in the '007 patent, the resulting peak-to-peak voltage for the 200 volts root mean square is 583 volts peak-to-peak. However, using the conversion factor of 2 for a square wave, the 200 volts root-mean-square converts to 400 volts peak-to-peak.

of the return electrode in the Slager article. (See id. at 1414-18) Given this evidence of the differences between these prior art references and the claimed invention, the jury verdict was not erroneous. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '592 patent is invalid on anticipation grounds.

The court also denies Smith & Nephew's motion for a new trial as to the '592 patent. None of the common reasons for granting a new trial exist under the facts at bar. That is, the jury's verdict is not against the weight of the evidence or facially inconsistent. Likewise, no miscarriage of justice will result if the verdict stands.

b. Invalidity on Enablement Grounds

The statutory basis for the enablement requirement is found in 35 U.S.C. § 112, paragraph 1, which provides in relevant part:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In order to be enabling, a specification must teach those skilled in the art how to make and to use the full scope of the claimed invention without undue experimentation. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997). The Federal Circuit has explained that "patent protection is granted in

return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable ... Tossing out the mere germ of an idea does not constitute enabling disclosure." Id. at 1366.

In determining whether undue experimentation is required to practice a claimed invention, a court may consider several factors, including: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (6) the predictability of the art; and (7) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Consideration of each of these factors, however, is not a mandatory part of a court's analysis. Rather, a court is only required to consider those factors which are relevant to the facts of each case. See Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991). Thus, the enablement requirement is a question of law based on underlying factual inquiries. In re Wands, 858 F.2d at 737.

Smith & Nephew argues that the asserted claims in the '882 patent are not properly enabled because the "cold ablation"

process is not adequately described in the specification.¹¹ The '882 specification states that the cold ablation process is dependent upon a variety of factors including "the number of electrode terminals, electrode size and spacing, electrode surface area, asperities and sharp edges on the electrode surfaces, electrode materials, applied voltage and power, current limiting means, such as inductors, electrical conductivity of the fluid in contact with the electrodes, density of the fluid, and other factors." ('882 patent, col. 11 at ll. 8-13) Smith & Nephew contends that while the requisite variables are enumerated in the specification, it fails, nevertheless, to specify what particular combination should be used to achieve optimal cold ablation. Smith & Nephew supports this argument with Dr. Taylor's testimony regarding preferred voltage ranges, materials, frequencies, fields, power levels, contract surface area values and distances for the active electrode. (See D.I. 416 at 1436-38)

The jury, however, reasonably may have disregarded Dr. Taylor's testimony, finding it to be both conclusory and entirely solicited by counsel's line of direct questioning. Dr. Taylor testified that he "blanked" on invalidity grounds other than

¹¹The cold ablation process involves "applying a high frequency voltage between the active electrode and the return electrode to develop high electric field intensities in the vicinity of the target tissue site." ('882 patent, col. 10 at ll. 41-44) The high electric field causes the tissue to completely disintegrate. (Id. at ll. 44-54)

anticipation; consequently, he was led into a discussion of enablement by trial counsel. In relevant part, Dr. Taylor testified as follows:

Q: Do you have any other basis for believing that the claims of the '882 patent are invalid?

A: I am sorry, I am blanking on this.

* * *

Q: Does the '882 patent teach anything about how to achieve a new phenomenon that is different than the principle of operation of conventional electrosurgical devices?

A: No, it doesn't. I was perplexed and, frankly, am still perplexed about the overall phenomenon of [c]oblation.

Q: And is that defense also sometimes called nonenablement?

A: Yes, it is.

Q: Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?

A: Yes, I have an opinion.

Q: What is that opinion?

A: That it is not.

Q: Thank you.

(Id. at 1323-1325) (emphasis added) Based on the above record, the jury had sufficient grounds to conclude that Smith & Nephew had failed to prove by clear and convincing evidence that the '882 patent was not enabled and invalid. In turn, the court denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on enablement grounds.

Regarding a new trial, the verdict was not against the clear weight of evidence. Likewise, the jury's verdict will not lead to a miscarriage of justice. Thus, the court denies Smith &

Nephew's motion for a new trial on enablement grounds as to the '882 patent.

E. Smith & Nephew's Motion for A New Trial on the Basis of Improperly Admitted/Excluded Evidence

Smith & Nephew contends that the court erred in admitting and excluding select evidence such that a new trial is warranted. Specifically, Smith & Nephew argues that the following evidence was improperly excluded: (1) Arthrocare's sworn 510(k) submissions to the Food and Drug Administration ("FDA"); (2) testimony regarding those submissions from Dr. Hira A. Thapliyal, a co-inventor named on the patents in suit; (3) testimony regarding the certificate of correction from Mr. Warren Heim, a consultant to Smith & Nephew from Team Medical; (4) Judge Orrick's opinion that the '198 patent anticipated one of the patents in suit; and (5) testimony from Dr. Manwaring regarding ultraviolet photon emission test results. Smith & Nephew also contends that evidence of copying and Smith & Nephew marketing documents were improperly admitted. Federal Rule of Civil Procedure 61 requires a court to disregard harmless evidentiary errors. In pertinent part, Rule 61 states:

No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial . . . unless refusal to take such action appears to the court inconsistent with substantial justice. The court at every stage of the proceeding must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.

A court's inquiry in evaluating a motion for a new trial on the basis of trial error is, therefore, twofold: "(1) whether an error was in fact committed, and (2) whether that error was so prejudicial that denial of a new trial would be 'inconsistent with substantial justice.'" Finch v. Hercules Inc., 941 F. Supp. 1395, 1414 (D. Del. 1996) (internal citation omitted). With respect to the second prong of this two-part test, a new trial must be granted unless "it is highly probable that [the erroneous ruling] did not affect the [objecting party's] substantial rights." Bhaya v. Westinghouse Electric Corp., 709 F. Supp. 600, 601 (E.D. Pa. 1989) (quoting McQueeney v. Wilmington Trust Co., 779 F.2d 916, 928 (3d Cir. 1985)).

The court has reviewed its rulings concerning the evidence in issue consistent with the first prong and finds no error was in fact committed. As such, the court need not consider whether denial of a new trial would be inconsistent with substantial justice as set forth in the second prong. The court considers each item of evidence in dispute in further detail below.

1. Exclusion of Arthrocare's FDA 510(k) Submissions and Dr. Thapliyal's Testimony

Smith & Nephew argues that Arthrocare's 510(k) submissions to the FDA and Dr. Thapliyal's testimony regarding those submissions qualify as admissions against interest by a party opponent and should have been admitted into evidence as relevant

to the issues of anticipation and enablement.¹² In particular, Smith & Nephew charges that the submissions demonstrate that the commercial embodiments of the patents in suit have the same principles of operation as prior art devices. The court rejects Smith & Nephew's argument and maintains that these submissions are irrelevant to invalidity, just as the court originally concluded when it ruled on Smith & Nephew's motion in limine. (See D.I. 367 at ¶15; D.I. 410 at 193) Anticipation is determined by comparing the limitations of the asserted claims, not of commercial embodiments as described in 510(k) submissions, to the disclosure found in a single piece of prior art. Enablement is evaluated based on the teachings found in the specification, not on those present in 510(k) submissions. Therefore, since the 510(k) submissions are not relevant to the substantive issues at bar, the exclusion of these documents and corresponding testimony was not in error. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Arthrocare's 510(k) submissions and Dr. Thapliyal's testimony about these submissions.

¹²A 510(k) submission to the FDA is a "submittal[] of engineering and clinical information which [is] provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market." Sunrise Med. HHG, Inc. v. AirStep Corp., 95 F. Supp. 2d 348, 405 (W.D. Pa. 2000).

2. Exclusion of Mr. Heim's Testimony

Smith & Nephew argues that it sought to introduce testimony at trial from Mr. Heim to support its argument that the certificate of correction was invalid. Specifically, Smith & Nephew contends that Mr. Heim was prepared to testify that he did not recognize the possibility of an error in the "active electrode" claim language found in the '882 patent as originally issued prior to the certificate of correction. On review, the court finds that its decision to limit Mr. Heim's testimony to the subject matter of his deposition was correct.

Federal Rule of Civil Procedure 37(c)(1) provides in pertinent part:

A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.

The court excluded this testimony because Mr. Heim did not discuss the substance of his trial testimony in his deposition. That is, approximately one week prior to the start of trial, Arthocare deposed Mr. Heim and asked him what he expected to testify about at trial. Smith & Nephew counsel instructed Mr. Heim not to respond to the question citing attorney-client privilege and the work product doctrine. Finding such instruction to be improper gamesmanship under Rule 37(c), the

court limited Mr. Heim's testimony to the substance of his deposition testimony. (See D.I. 413 at 944) Additionally, the court is troubled by Smith & Nephew's use of Mr. Heim's testimony. Despite identifying him as a fact witness, Smith & Nephew appears to employ him as an expert concerning the validity of the certificate of correction. (See id. at 939) In light of both these concerns, the court denies Smith & Nephew's motion for a new trial on grounds that Mr. Heim's testimony was improperly limited.

3. Exclusion of Judge Orrick's Opinion

Smith & Nephew argues that the findings of fact relating to the '536 and '882 patents made by Judge Orrick following a preliminary injunction hearing during the course of the Arthocare v. Ethicon, Inc. litigation are relevant to both the presumption of validity and the validity of the '536 and '882 patents. In particular, Smith & Nephew charges that Judge Orrick's determination that the '198 patent describes "a bipolar electrosurgery device intended to be used in electrically conductive fluid, with electrical current flowing between the active and return electrodes through the fluid" should have been admitted since the parties at bar dispute whether the '198 patent discloses electrically conducting fluid. (D.I. 321, ex. A at 17) The court disagrees. Judge Orrick rendered his findings of fact in the context of a preliminary injunction motion and concluded

that there were substantial questions about the validity of claim 45 of the '536 patent, claims 1, 26, 28, and 32 of the '882 patent, claims 40 and 44 of the '909, and claim 101 of the '281 patent. His interlocutory decision does not alter the presumption of validity; a patent is presumed valid and remains so unless and until final judgment is entered otherwise. See 35 U.S.C. §282 (2003). Additionally, findings of fact made in litigation unrelated to the present suit do not have a presumptive effect. In the instant litigation, the jury was charged with determining the validity of the asserted patents after considering the evidence presented at trial in accordance the court's instructions. Any reference to Judge Orrick's opinion potentially would have confused the jury regarding their role in deciding such validity. Moreover, the burdens of proof associated with a preliminary injunction hearing differ from those employed at trial. In this regard, the Federal Circuit has observed that "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial."

Amazon.com v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1358 (Fed. Cir. 2001). Consequently, the court denies Smith & Nephew's motion for a new trial on the basis the exclusion of Judge Orrick's opinion.

4. Limitation of Dr. Manwaring's Testimony To His Expert Report

Smith & Nephew contends that Dr. Manwaring should have been permitted to testify at the trial about whether the Codman ME2¹³ emits ultraviolet photons and about testing conducted by Dr. Skromme to prove such emission. Smith & Nephew argues that this testimony was relevant to enable the jury to assess whether the Codman ME2 anticipates the asserted claims that have ultraviolet photon emissions as a limitation. However, Smith & Nephew did not produce Dr. Skromme's report until two days before Dr. Manwaring was scheduled to testify after the start of trial. Because Arthrocare was not afforded the opportunity to take discovery on the test results or to depose Dr. Skromme, the court excluded such evidence at trial, consistent with Rule 37(c)(1). The court, therefore, denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Dr. Manwaring's testimony about ultraviolet photon emission testing.

5. Admission of Evidence of "Copying"

Smith & Nephew argues that admission of evidence of "copying" infected the entire trial and improperly inflamed the jury. In this regard, Smith & Nephew employees read the patents in suit and evaluated Arthrocare's patented products prior to

¹³The Codman ME2 is a commercial product embodied by the '158 or '138 prior art patent.

designing the accused products. (See D.I. 412 at 626-633; D.I. 415 at 1160-61; D.I. 417 at 1507-1508)

Prior to trial, in order to avoid any inferences of copying, Smith & Nephew made the strategic decision to withdraw its defense of obviousness and to stipulate to its knowledge of the patents in suit. Nevertheless, after a vigorous motion practice and lengthy discussions, the court concluded that the evidence was still relevant to the issue of inducing infringement. More specifically, in order to prove that Smith & Nephew induced infringement, it was Arthrocare's burden to prove that Smith & Nephew intended to encourage or to instruct its customers to directly infringe. Evidence of copying was appropriate circumstantial evidence going to intent; that is, if Smith & Nephew used Arthrocare's patented products as a template for its own, that would be circumstantial evidence that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit by using the Saphyre, ElectroBlade, and Control RF probes.¹⁴

At trial, Smith & Nephew presented evidence that it is customary and not inappropriate to evaluate competitors'

¹⁴It is ironic that Smith & Nephew, post-trial, argues that Arthrocare has not satisfied its burden of proving intent, based on the very evidence described above. See supra, Section IV, C, 5. Clearly, then, the fact of knowledge is not a sufficient basis for proving inducement and the evidence of intent is relevant.

products, and that it designed its own products without copying Arthrocare's patented products. (See D.I. 412 at 651-54; D.I. 414 at 951-53; D.I. 417 at 1507-08) Smith & Nephew was not prejudiced with respect to its ability to present the technical merits of its noninfringement and invalidity defenses to the jury. (See, e.g., D.I. 412 at 715-32; D.I. 414 at 805-822, 883-896, 962-970; D.I. 415 at 976-983; 999-1039; 1198-1227; D.I. 416 at 1288-1334; D.I. 417 at 883-896) Arthrocare, in turn, presented evidence to the contrary. (See, e.g., D.I. 411 at 376-500) Given the time spent on this noninfringement and invalidity evidence during the course of a nine-day jury trial, it cannot be said that disputed evidence relating to "copying" was disproportionately emphasized or time-consuming.

For all of these reasons, the court concludes that it was not error to admit evidence of "copying" and that such admission does not present grounds for a new trial.

6. Admission of Smith & Nephew Marketing Documents¹⁵

¹⁵Smith & Nephew failed to identify precisely which marketing documents that it believes were erroneously admitted. The court, consequently, is left to presume that Smith & Nephew is uniformly referring to any marketing type of document entered into evidence including the "Dyonics Control RF System" Sales Guide, "Saphyre Bipolar Ablation Probes" Sales Guide, "Instructions for Use Dyonics Series 7000 RF Arthroscopic Probe," "Competitive Selling Arthrocare," and the "Dyonics Series 9000 Electrode Blade Resector." (See, e.g., PX 593, PX 390, PX 205, PX 324, PX 335)

Smith & Nephew claims that admission of its marketing documents, which appear to characterize Arthrocare's patent position as "strong," were irrelevant and inflammatory. Smith & Nephew contends that these documents could only be relevant to the issues of obviousness and its knowledge of the patents, but that neither were in dispute at trial.¹⁶ Moreover, Smith & Nephew argues that the opinions of its marketing and sales personnel regarding the strength of Arthrocare's patents are irrelevant.

The court finds that Smith & Nephew's marketing documents are relevant to the inducing infringement cause of action and, as such, that it did not err in admitting this evidence at trial. As the court discussed above in relation to evidence of "copying," Smith & Nephew's marketing documents are circumstantial evidence of Smith & Nephew's intent to induce infringement. These documents show how the alleged infringing products function and give instruction how to operate them. The court concludes that such information bears upon the manner in which Smith & Nephew encouraged its users to infringe Arthrocare's patents. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis the court's admission of Smith & Nephew's marketing documents.

¹⁶As mentioned above, Smith & Nephew withdrew its obviousness defense prior to trial and stipulated to its knowledge of the patents in suit during trial.

**F. Smith & Nephew's Motion for A New Trial on the Basis of
The Court's Jury Instructions**

Smith & Nephew asserts that the court's instruction on infringement was "hopelessly confusing" for the jury when read in light of the court's claim construction for the "contact" limitation recited in claim 47 of the '536 patent and all of the asserted claims of the '592 patent.¹⁷ The court instructed the jury as follows concerning infringement:

In this case, Arthocare contends that Smith & Nephew's accused products and methods literally infringe the asserted claims. In order to prove that any one of the asserted claims is literally infringed, Arthocare must prove by a preponderance of the evidence that Smith & Nephew's accused products or methods include each and every limitation of that particular claim. In other words, you must compare the features of the accused products or methods with the limitations of each asserted claim in order to determine whether the accused products or methods include each and every limitation of an asserted claim.

With respect to the asserted claims of the '592 and '882 patents, the accused methods need not always practice the invention of any asserted method claim, so long as Arthocare has proven by a preponderance of the evidence that the accused methods operate in a way that meet each and every step of the method described in the claim some of the time.

(D.I. 418 at 1716) The court further instructed the jury as follows concerning the "contact" limitation:

The claim limitation the return electrode is not in contact with the body structure is clear -- the return electrode is not to contact the body at all during the performance of the claimed method. The claimed method

¹⁷Smith & Nephew objected to the these instruction at the charge conference. (See D.I. 416 at 1239-1241; D.I. 417 at 1469-1473)

does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed.

(Id. at 1718) Specifically, Smith & Nephew appears to argue that the source of the confusion lies in the juxtaposition of the language "at all" in the infringement instruction with the language "some of the time" in the claim construction instruction. Smith & Nephew argues that the jury may have read these instructions and thought that infringement occurred if the return electrode was not always in contact with the tissue.

Where the basis for seeking a new trial is an alleged error in the jury instructions, the error must be "so substantial that, viewed in light of the evidence in the case and the charge as a whole, the instruction was capable of confusing and thereby misleading the jury." Link v. Mercedes-Benz of North America, Inc., 788 F.2d 918, 922 (3d Cir. 1986). After reviewing the jury charge as a whole in light of the evidence presented in this case, the court cannot conclude that the jury instructions confused or misled the jury into believing that the accused products infringe the asserted claims if they are not in continual contact with tissue to warrant a new trial. The court instructed the jury separately regarding infringement and its claim construction, and both instructions properly stated the law. As well, the jury was asked to complete a special verdict form that explicitly separated the types of infringement, the

patents in suit, the asserted claims of each patent, and the accused infringing products. As a result of this separation, the jury was required to make finite determinations concerning whether a particular claim in a particular patent was infringed in a particular way by a particular product. Furthermore, the court finds no evidence to suggest that the jury was "hopelessly confused." The jury did not ask the court to clarify any of its instructions or pose any questions to the court during deliberations. The jury also did not incur any difficulty in completing the special verdict form as they entered responses in all required fields. (See D.I. 405) Therefore, the court denies Smith & Nephew's motion for a new trial on the basis of the court's jury instructions.

G. Smith & Nephew's Motion for A New Trial On the Grounds That the Validity of the Certificate of Correction Was Decided by the Jury

Smith & Nephew avers that the district court is better suited to decide the validity of the certificate of correction than a jury because such determination involves both a review of the factual determinations of a government agency and the legal decisions about the nature of the underlying mistake. The court disagrees. Smith & Nephew did not object to submitting this issue to the jury at any time during the trial or prior to the jury charge. Smith & Nephew appears now to raise this objection in the face of an unfavorable jury verdict. Even assuming,

arguendo, that the court did err in submitting this issue to the jury, the court, nevertheless, agrees with the jury's verdict that the certificate of correction is valid. The court, consequently, denies Smith & Nephew's motion for a new trial on the grounds that the validity of the certificate of correction was decided by the jury.

H. Smith & Nephew's Motion for A New Trial on the Basis of Arthrocare's Refusal to Limit the Issues at Bar

Smith & Nephew complains that it was allocated insufficient time to adequately try the number of issues presented by Arthrocare. As described by Smith & Nephew, Arthrocare asserted sixteen claims from three patents against three Smith & Nephew products.¹⁸ As a result, according to Smith & Nephew, the verdict form required the jury to make 107 separate factual findings, which it did in only 4.5 hours, thereby spending just over two minutes per finding.¹⁹

¹⁸In reality, Arthrocare asserted only six independent claims from three patents. All three patents involved the same technology and contained many identical claim limitations. Indeed, two of the patents share the same specification.

¹⁹Making such arguments is a dangerous business in Delaware, where so many patent cases are tried. The court could, for instance, cite to the case of KLA-Tencor Corporation v. ADE Corporation, Civ. No. 00-892-KAJ, where the jury returned a verdict in February 2004 on 17 issues in approximately 37 minutes, likewise spending just over two minutes per finding. The court suspects, however, that counsel for Smith & Nephew will not be complaining about that result, since it was favorable to its client in that case.

The court starts with the proposition, not really in issue here, that a district court has the inherent power to manage its docket. See, e.g., Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 609 (3d Cir. 1995). There are a finite number of trial hours in a calendar year. If the court failed to manage its caseload, parties would get to trial in four or five years, rather than 18 to 24 months. Therefore, in every civil case, the court determines the number of hours in which each party will be required to present its evidence and arguments to the jury. This decision is based on the court's calendar, its experience, and its review of the pretrial order submitted by the parties at bar. The number of hours allocated to the instant case was fair, based upon that review.²⁰ The record demonstrates that it was not lack of time that dictated the results in this case,²¹ but the evidence presented by Arthrocare. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of Arthrocare's refusal to limit the issues at bar.

²⁰The court had assigned several more hours to this case, but postponed trial for a day (and, thus, reduced the total number of hours available for trial) at Smith & Nephew's request. In connection with this latter request, made the day before trial commenced, the court tried to, but could not, accommodate a further postponement of trial, based on a multitude of considerations, as discussed with counsel. (See D.I. 382, 390, 409)

²¹The court notes in this regard that Smith & Nephew's decision to dismiss its obviousness defense was as much related to evidentiary concerns as it was to trial management concerns. (See D.I. 409 at 16-17; see also supra, Section IV, E, 5)

I. Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct and Smith & Nephew's Cross Motion to Strike Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct²²

Smith & Nephew alleges that Arthrocare committed inequitable conduct for each of the patents in suit: (1) during the prosecution of the '592 patent by informing the examiner that the '198 patent did not disclose the use of electrically conductive fluid and by not disclosing Judge Orrick's opinion; (2) during the reexamination of the '536 patent by failing to disclose Smith & Nephew's summary judgment briefs, Dr. Taylor's expert report, and the Roos declaration directed toward the issue of invalidity, and by engaging in improper "off-the-record" telephone conversations with the examiner regarding the merits of the '536 reexamination prior to the first substantive exam; and (3) during the process of obtaining the certificate of correction for the '882 patent by making two affirmative misrepresentations and by failing to explain how the so-called "correction" would broaden the scope of the claims.²³ Smith & Nephew charges that Mr. John Raffle,

²²Since the parties' cross motions are interrelated and focus of the issue of inequitable conduct, the court will consider their respective arguments together.

²³In granting the parties' request to file motions regarding inequitable conduct, the court indicated that such briefing was to be based upon the record established at trial. Therefore, to the extent that either party raised evidence not of record in their respective motions at bar, the court will ignore such evidence in deciding the instant motions. The court notes that Smith & Nephew seeks leave to depose the examiner responsible for

Arthrocare's in-house counsel responsible for prosecution of the '592 patent, misled the examiner concerning the use of electrically conductive fluid. Smith & Nephew claims that Mr. Raffle knew that claim 1 of the '198 patent recited "liquid to provide electrical conductance," but failed to call the examiner's attention to this limitation. In response to a February 29, 2000 office action issued by the examiner,²⁴ Mr. Raffle instead responded that "[t]he '198 patent never describes the use of 'electrically conductive fluid' during electrosurgery. The Roos '198 [p]atent only discloses the use of an unspecified 'washing liquid' that flows through the endoscope that houses the treatment and neutral electrodes. . . . The Roos '198 [p]atent does not state that the 'washing liquid' that is supplied to the region of the surgical site is electrically conductive fluid." (D.I. 428, ex. B at B23) Mr. Raffle also directed the examiner's attention to the '667 patent to substantiate his argument since this reference explains that "the device described in the

the reexamination of the '536 patent to determine the contents of his "off-the-record" conversation with Arthrocare's in-house counsel. The court denies this request.

²⁴The examiner stated:
Claims 80, 81, 83-85 . . . are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roos The device includes a spaced return electrode as shown by Figure 1. A washing fluid passes through the axial lumen of the device. Since the return electrode is removed from the body structure, a conductive fluid must complete the current flow path.
(D.I. 428, ex. B at B17)

. . . '198 [p]atent[] did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive." (*Id.* at B24) Smith & Nephew further argues that Arthrocare's inequitable conduct in connection with any one of the '592, '536, or '882 patents taints the enforceability of the remaining patents in suit. Arthrocare rebuts these assertions in their entirety and moves the court to enter a judgment of no inequitable conduct.

Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the PTO. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a) (2003). This duty is predicated on the fact that "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The duty of candor, good faith, and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). A breach of this duty constitutes inequitable conduct. Mollins, 48 F.3d at 1178. If it is established that a patent applicant engaged in inequitable conduct with respect to one claim, then

the entire patent application is rendered unenforceable.

Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). A trial court may look beyond the final claims to their antecedents in determining inequitable conduct. Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803 (Fed. Cir. 1990). "Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it." Kingsdown, 863 F.2d at 874 (footnote omitted).

In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; or (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the PTO. Mollins, 48 F.3d at 1178. A determination of inequitable conduct, therefore, entails a two step analysis. First, the court must determine whether the withheld information meets a threshold level of materiality. A reference is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. Allied Colloids, Inc. V. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995) (citations omitted). . A

reference, however, does not have to render the claimed invention unpatentable or invalid to be material. See Merck v. Danbury Pharmacal, 873 F.2d 1418 (Fed. Cir. 1989).

After determining that the applicant withheld material information, the court must then decide whether the applicant acted with requisite level of intent to mislead the PTO. See Baxter Int'l, Inc. V. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent." Herbert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. A "smoking gun" is not required in order to establish an intent to deceive. See Merck, 873 F.2d at 1422. An inference of intent is warranted where a patent applicant knew or should have known that the withheld information would be material to the PTO's consideration of the patent application. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

Once materiality and intent to deceive have been established, the trial court must weigh them to determine whether the balance tips in favor of a conclusion of inequitable conduct.

N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1988). The showing of intent can be proportionally less when balanced against high materiality. Id. In contrast, the showing of intent must be proportionally greater when balanced against low materiality. Id.

If an original patent is found unenforceable for inequitable conduct, descendent patents which are genealogically related to the original patent, such as continuations, continuations-in-part, or divisionals, may also be rendered unenforceable. See East Chicago Mach. Tool Corp. v. Stone Container Corp., 181 U.S.P.Q. 744, 748 (N.D. Ill. 1974). This theory of unenforceability has been termed "infectious unenforceability" by district courts and recognized by the Federal Circuit. See Baxter, 149 F.3d at 1327. It is premised on the guiding principle that "the duty of candor extends through the patent's entire prosecution history," and that a breach of the duty of candor "may render unenforceable all claims which eventually issue from the same or a related application." Fox, 922 F.2d at 803-04. Charges of infectious inequitable conduct are disfavored even more than charges of inequitable conduct. Eaton Corp. v. Parker-Hannifin Corp., 2003 U.S. Dist. LEXIS 1014, *2 (D. Del. Jan. 24, 2003). To prove infectious unenforceability, an accused infringer must establish "inequitable conduct sufficient to hold at least one patent

unenforceable before [a court will] consider[] whether to hold an entire group of related patents unenforceable." Speedplay, Inc. V. Bebop Inc., 211 F.3d 1245, 1259 (Fed. Cir. 2000). If this threshold requirement is met, then the accused infringer must demonstrate an "immediate and necessary relation" between the alleged inequitable conduct and enforcement of the related patents. Ronald A. Katz Tech. Licensing, L.P. v. Verizon Communications Inc., 2002 U.S. Dist. LEXIS 12982, *7-8 (E.D. Pa. July 16, 2002) (internal citations omitted).

The court concludes that Arthocare did not commit inequitable conduct during the prosecution of the '592 patent, during the reexamination of the '536 patent, or in conjunction with the certificate of correction for the '882 patent. Considering the '592 patent, the court notes that the use of electrically conductive fluid is material to the patentability of the '592 invention given that it appears as a limitation in the asserted '592 patent claims. The court does not find that Mr. Raffle, however, intended to deceive the PTO concerning the '198 patent. Smith & Nephew presented no evidence of record to show that Mr. Raffle purposefully misrepresented material facts or submitted false material information about this prior art reference. Rather, the record shows that Mr. Raffle provided this prior art reference to the PTO for consideration during the prosecution of the '592 patent. (See D.I. 428, ex. B at B27)

The examiner was free to reach his own conclusions regarding the teachings contained in this reference.²⁵ (See id. at B23-26) Indeed, the Federal Circuit has opined that an examiner is free to accept or reject an inventor's interpretation of the teachings of a reference. Life Techs., Inc. V. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000). Mr. Raffle's statements about electrically conductive fluid merely reflected his understanding of the '198 patent.

As to Judge Orrick's opinion, the court concludes yet again that it was not material to the patentability of the '592 patent. The opinion was preliminary in nature since it was issued pursuant to Arthrocare's motion for a preliminary injunction. It likewise did not directly address the anticipatory effects of the '198 patent on the application that was granted as the '592 patent. Rather, Judge Orrick found that the '198 patent raised substantial questions as to the validity of select claims of patents other than the '592 patent, namely, the '536 patent and the '281 patent.

Even assuming, arguendo, that Judge Orrick's opinion was material, Arthrocare complied with its duty of disclosure under the Manual of Patent Examining Procedure ("MPEP") Section 2001.06(c). This section states that

²⁵The examiner ultimately concluded that the '198 patent did not disclose electrically conducting fluid. (See id. at B40-41)

[w]here the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office. . . . At a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or 'fraud,' or 'inequitable conduct' relating to the original patent, and the nature of litigation material relating to these issues. Enough information should be submitted to clearly inform the Office of the nature of the issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation.

MPEP § 2001.06(c) (2003). Arthocare submitted a list of documents from the Arthocare v. Ethicon, Inc. litigation to the PTO. This list included Judge Orrick's opinion. (See id. at B7, ¶40) The court cannot conclude that Arthocare intended to deceive the PTO concerning Judge Orrick's opinion given its compliance with Section 2001.06(c). Accordingly, the court grants Arthocare's motion for entry of judgment of no inequitable conduct as to the '592 patent and denies Smith & Nephew's cross motion to strike Arthocare's motion for entry of judgment of no inequitable conduct as to the '592 patent.

Turning to the '536 patent, the court finds that Arthocare did not intend to deceive the PTO concerning its suit against Smith & Nephew or conceal Smith & Nephew's primary arguments concerning validity and enforceability. In compliance with Section 2001.06(c), Arthocare notified the PTO about the litigation at bar and presented Smith & Nephew's invalidity

arguments in three separate communications, namely: (1) an Information Disclosure Statement dated October 12, 2001 disclosing Smith & Nephew's primary invalidity and unenforceability arguments; (2) a second Information Disclosure Statement dated June 6, 2002 disclosing Smith & Nephew's June 3, 2002 supplemental invalidity contentions in the form of Smith & Nephew's response to Arthrocare's contention interrogatories; and (3) a third Information Disclosure Statement dated December 19, 2002 attaching Smith & Nephew September 10, 2002 invalidity contentions. (See D.I. 428, ex. B at 76-87; 97-230; 290-341) Although these disclosures did not specifically include the summary judgment motions or expert reports in dispute, such documents were cumulative in nature with Smith & Nephew's invalidity contentions already before the PTO. Rule 56(b) states that "information is material to patentability in a reexamination proceeding when it is not cumulative to information already of record or being made of record in the reexamination proceeding." 37 C.R.F. §1.56 (2004). The Federal Circuit has also held that "[a] reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991) (citing Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991)). In addition, the court notes

that these documents were designated "highly confidential" and were subject to the parties' stipulated protective order. This protective order limited the use of "highly confidential" information to persons or entities "to whom such information is disclosed solely for the purposes of this action, and not for any other action or for any business, patent prosecution, licensing, competitive, or governmental purpose or function, and such information shall not be disclosed to anyone except as provided in this [p]rotective [o]rder." (D.I. 40 at ¶6) The in-house corporate counsel who prosecuted the '536 patent during reexamination (i.e., Mr. Raffle and Mr. Sanjay Bagade), consequently, were not privy to "highly confidential" documents. The court, therefore, reasons that Arthrocare's in-house counsel did not intend to deceive the PTO about Smith & Nephew's summary judgment motions and expert reports because they likely were unaware of the existence of these documents.

As to Arthrocare's "off-the record" conversations with the examiner during the '536 reexamination prior to the first office action,²⁶ there is no evidence of record to suggest that Arthrocare's in-house counsel violated 37 C.R.F. § 1.56 or MPEP § 2281. Interviews about the patentability of claims involved in an ex parte reexamination proceeding ordinarily are not conducted

²⁶The examiner issued the first office action on September 24, 2002.

prior to the first office action. See 37 C.R.F. § 1.56 (2004); see also MPEP § 2281 (2001). However, interviews are "permitted where the examiner initiates the interview for the purpose of providing an amendment to make the claims patentable and the patent owner's role is passive. The patent owner's role . . . is limited to agreeing with the change or not." Id. Additionally, 37 C.R.F. § 1.56 and MPEP § 2281 require the patent holder to file a written statement of the substance of the interview with the PTO. In accordance with these rules, Mr. Bagade submitted a statement on December 19, 2002 to summarize various communications with the examiner. While the exact number of conversations between Arthrocare's in-house counsel and the examiner and the dates of such conversations are not clear from the contents of Mr. Bagade's statement, it is evident that at least one occurred prior to the first office action because Mr. Bagade stated that the examiner contacted him in May 2002. (See D.I. 462, ex. B at 228-230) This interview, nevertheless, was consistent with the requirements of MPEP § 2281. That is, the examiner contacted Mr. Bagade for purposes of discussing an amendment to claim 1 of the '536 patent, and Mr. Bagade responded by not agreeing to the amendment. (See id.)

Even though the court cannot identify with certainty the time frames for the remaining interviews of record, the court concludes that the record does not suggest that Mr. Raffle caused

the examiner to "parrot back, verbatim" the arguments that he made with respect to the '198 patent during the earlier prosecution of the '592 patent as alleged by Smith & Nephew, despite his discussions with the examiner about the '198 patent, the '667 patent, and Judge Orrick's opinion.²⁷ Under patent office rules, a patent examiner is charged with a duty to independently conduct a thorough examination.

On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

37 C.R.F. §1.104(a)(1) (2004). The Federal Circuit "presumes that the Patent Office complies with its own rules, a presumption overcome only upon presentation of contrary evidence." Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1103 (Fed. Cir.) (citing Rite Hite Corp. v. Kelley Co., Inc., 819 F.2d 1120, 1123 (Fed. Cir. 1987)). In line with this duty, the examiner placed his initials next to the '198 patent on the Form PTO-1449, indicating that he considered the patent. The examiner confirmed

²⁷Additional communications of record entailed procedural concerns, such as the status of the reexamination proceedings, filing of information disclosure statements, and an estimate of when the PTO would provide the first office action.

this review in a November 15, 2002 office action, stating that he engaged in "careful[] consideration and review of the Roos '198 patent." (PX 7 at 214) Therefore, without evidence of indiscretion during the '536 reexamination proceeding, the court finds that Smith & Nephew's allegations regarding inequitable conduct based on off-the-record conversations to be without merit. Consequently, the court grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent.

Focusing on the '882 patent, the court finds no evidence in the record to substantiate Smith & Nephew's allegations that Mr. Raffle intentionally misled the PTO when he asserted that he amended all claims to replace the term "active electrode" with "electrode terminal" or when he presented an antecedent basis argument as grounds to amend application claim 23 (i.e., issued claim 1) but did not point out other instances of improper antecedent basis within the claim set. Mr. Raffle filed a supplemental amendment during the prosecution of the '882 patent to change "active electrode" to "electrode terminal" and "electrically conducting liquid" to "electrically conducting

fluid."²⁸ (See DTX 306 at C2-C12) He missed one correction of "active electrode" in application claim 23 and one instance of the same correction in application claim 52. Recognizing these mistakes after reviewing the '882 patent on the day it issued, Mr. Raffle filed a request for certificate of correction the following day. (See 1527, DTX 306 at C13-C15) In his request, Mr. Raffle explained that he mistakenly forgot to replace the term "active electrode" with "electrode terminal" in one place in application claim 23 and that such failure potentially created an antecedent basis problem. (See DTX 306 at C13) Given this sequence of events, the court concludes that Mr. Raffle made honest mistakes in amending the claims; he did not craft claims to read on Ethicon's products in order to file an infringement action against Ethicon. The court, consequently, grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '882 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '882 patent.

Finally, because the court has not found Arthrocare liable for inequitable conduct with respect to any of the individual patents in suit, the court declines to hold them collectively unenforceable based upon an alleged pattern of inequitable

²⁸Mr. Raffle replaced seventeen of the nineteen occurrences of the term "active electrode," including three in application claim 23 and two in application claim 52.

conduct. Even if the court had found just one patent invalid on inequitable conduct grounds, the court is not convinced that Smith & Nephew would be able to show an "immediate and necessary relation" between the inequitable conduct associated with that one patent and the enforcement of the other two patents. To establish the requisite relatedness, Smith & Nephew relies on the fact that the three patents in suit share the same inventors, concern the same electrosurgical system, have been licensed together, and were asserted concurrently in the instant litigation. Nevertheless, this court agrees with the Eastern District of Pennsylvania's holding that "[m]ere relatedness of subject matter' is insufficient to establish this [immediate and necessary] relationship." Id. (citing Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 810-811 (Fed. Cir. 1990)). In cases where courts found infectious unenforceability, there was greater connection between the act that triggered the inequitable conduct finding and the other patents in suit than in the case at bar. For example, in Consol. Aluminum Corp. 910 F.2d 804, the Federal Circuit held that the intentional fabrication of a fictitious best mode in one patent rendered three other patents with intertwined prosecution histories, two of which were continuations-in-part of the third, unenforceable. The court, therefore, grants Arthrocare's motion for entry of judgment of no inequitable conduct and denies Smith & Nephew's cross motion to

strike Arthrocare's motion for entry of judgment of no inequitable conduct on infectious unenforceability grounds.

J. Arthrocare's Motion for a Permanent Injunction

Arthrocare moves for entry of a permanent injunction to enjoin Smith & Nephew from directly infringing, contributing to the infringement, and inducing the infringement of the '536, '592, or '882 patents (1) by making, using, offering to sell, selling, marketing, advertising, or promoting in the United States or importing into the United States all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit; and (2) by instructing, training, or otherwise actively encouraging others in the United States to use all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit. The framers of the Constitution of the United States recognized that a patentee has the right to exclude others from practicing a patented invention. As a result of this belief, the framers adopted Clause 8 of Section 8, Article I which states: "The Congress shall have power . . . to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. art. I, § 8. Congress used their power to enact 35 U.S.C. § 283. This provision of law authorizes a court to "grant injunctions in accordance with the

principles of equity to prevent the violation of any right secured by patent, on such terms as the [c]ourt deems reasonable." 35 U.S.C. § 283.

In a patent infringement suit, a district court may grant a preliminary injunction pending trial or a permanent injunction "after a full determination on the merits." High Tech. Med. Instr., Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1554 (Fed. Cir. 1995). Indeed, the Federal Circuit has indicated that once a finding of infringement has been made, then an injunction should issue absent a sufficient reason for denying it. Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1247 (Fed. Cir. 1989). Courts, therefore, are given wide latitude in framing injunctive relief. KSM Fastening Sys., Inc. v. H.A. Jones Co., 776 F.2d 1522, 1527 (Fed. Cir. 1985). Nonetheless, consistent with the equitable nature of a permanent injunction, the court "must consider all circumstances, including the adequacy of the legal remedy, irreparable injury, whether the public interest would be served, and the hardship on the parties and third parties. E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 659 F. Supp. 92, 94 (D. Del. 1987). Additionally, Rule 65(d) of the Federal Rules of Civil Procedure requires an injunction to "set forth the reasons for its issuance, be specific in its terms, and shall describe in reasonable detail, and not by reference to the complaint or other document, the act

or acts sought to be restrained; and is binding only upon the parties to the action." Fed. R. Civ. P. 65(d).

In the instant case, the court finds Arthocare will suffer irreparable harm without a permanent injunction to prevent Smith & Nephew from practicing its patented inventions. As best stated by the Federal Circuit in H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384 (Fed. Cir. 1987):

In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement . . . The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the patentee whole, for the principal value of a patent is its statutory right to exclude.

Id. at 390.

Additionally, the public interest in preserving incentives to advance science and useful arts favors entry of an injunction to bar any further infringement by Smith & Nephew. The court recognizes that intellectual property law is premised on the desire to give inventors an incentive to invent and to reap the benefits of their labor. To this end, the Federal Circuit has previously noted that

[o]ne of those benefits is the right to prevent others from practicing what they have invented. Otherwise, if inventors cannot depend on their patents to exclude others, we fear that research and development budgets in the science and technology based industries would shrink, resulting in the public no longer benefitting from the labors of these talented people.

E.I. DuPont de Nemours v. Polaroid Graphics Imaging, Inc., 706 F. Supp. 1135, 1146 (D. Del. 1989). Under the facts at bar, Arthrocare created the market for electrosurgery probes by launching its first bipolar radio frequency ablation product for arthroscopic surgery in 1995. (See PX 450 at 3) Smith & Nephew later joined this market. (See PX 593 at 24, 39)

Finally, the court notes that removing the Saphyre, ElectroBlade, and Control RF probes from the stream of commerce will not harm or cause hardship to the public since Arthrocare, along with several other suppliers like Mitek and Stryker, offer alternative viable probes. As well, Smith & Nephew has already pulled the Control RF product from the market and only just recently launched the ElectroBlade and Saphyre products. The fact that Smith & Nephew may suffer a loss in revenue is not of concern. Indeed, the Federal Circuit has commented that just because an injunction might put an infringer out of business does not justify denying it. See Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 (Fed. Cir. 1986). "One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Id. Therefore, concluding that all relevant factors weigh in favor of granting a permanent

injunction, the court grants Arthrocare's motion for a permanent injunction.²⁹

V. CONCLUSION

For the reasons stated, the court denies Smith & Nephew's motion for judgment as a matter of law, motion for a new trial, and motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct. The court also denies Smith & Nephew's motion to modify the protective order. The court grants Arthrocare's motion for entry of judgment of no inequitable conduct and motion for entry of a permanent injunction. An order shall issue.

²⁹The court notes that Smith & Nephew's antitrust counterclaims are no longer pending before the court and will not be adjudicated in phase two. The court granted Arthrocare's motion to dismiss Smith & Nephew's antitrust counterclaims in a separately issued memorandum opinion. For this reason, the court concludes that it is not premature to issue a permanent injunction at this time.

(484)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

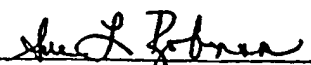
O R D E R

At Wilmington, this ~~10th~~ day of March, 2004, consistent with
the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Smith & Nephew's motion for judgment as a matter of law pursuant to Rule 50(b) is denied. (D.I. 458)
2. Smith & Nephew's motion for a new trial pursuant to Rule 59 is denied. (D.I. 455)
3. Arthrocare's motion for entry of judgment of no inequitable conduct is granted. (D.I. 427)
4. Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct is denied. (D.I. 437)
5. Arthrocare's motion for a permanent injunction is granted. (D.I. 424)

6. Smith & Nephew's motion to modify the protective order
is denied as moot. (D.I. 432)


United States District Judge

499

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

Civ. No. 01-504-SLR

O R D E R

At Wilmington this 8th day of April, 2004, having reviewed defendant's motion to lift stay to permit it to file an answering brief in opposition to plaintiff's motion to dismiss defendant's antitrust counterclaim, and the papers submitted in connection therewith;

IT IS ORDERED that said motion (D.I. 497) is denied, as it is untimely, having been filed well past the time for briefing the motion to dismiss and, indeed, after the court decided the motion to dismiss.


United States District Judge

506

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)
)
Plaintiff,)
)
v.) Civ. No. 01-504-SLR
)
SMITH & NEPHEW, INC.,)
)
Defendant.)

SMITH & NEPHEW, INC.,)
)
Counterclaim Plaintiff,)
)
v.)
)
ARTHROCARE CORPORATION and)
ETHICON, INC.,)
)
Counterclaim Defendants.)

REVISED ORDER

At Wilmington this 17th day of April, 2004, consistent
with the memorandum opinion issued on March 10, 2004;

IT IS ORDERED that:

1. Plaintiff's motion to dismiss defendant's antitrust counterclaims (D.I. 429) is granted.
2. Defendant/counterclaim plaintiff's antitrust

counterclaims are dismissed as to all counterclaim defendants.

John L. Robinson
United States District Judge

(501)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

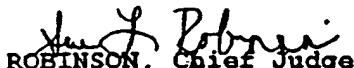
ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

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William J. Marsden, Jr., Esquire and Keith A. Walter, Jr., Esquire of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Mark J. Hebert, Esquire and Kurtis D. MacFerrin, Esquire of Fish & Richardson P.C., Boston, Massachusetts.

MEMORANDUM OPINION

Dated: April 21, 2004
Wilmington, Delaware


ROBINSON, Chief Judge

I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful direct, contributory, and inducing infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent"). (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (*Id.*) Smith & Nephew also asserted counterclaims for a declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended its answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219) By order dated November 27, 2002, the court stayed discovery and trial related to the antitrust counterclaims. (D.I. 206)

From April 30, 2003 through May 9, 2003, the

parties tried the issues of infringement and invalidity before a jury. The jury found by a preponderance of the evidence that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of claims 46, 47, and 56 of the '536 patent with its Saphyre, ElectroBlade, and Control RF products. (D.I. 405) The jury also found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 13, 17, and 54 of the '882 patent with its Saphyre, Saphyre with Suction, and Control RF products. (Id.) In addition, the jury found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent with its Saphyre, ElectroBlade, and Control RF products.¹ (Id.) The jury further found that Smith & Nephew did not prove by clear and convincing evidence that the patents in suit are invalid. (Id.)

Following this verdict, the parties filed numerous post-trial motions. Smith & Nephew, in particular, challenged every issue that the jury decided and also nearly every issue that the court decided. The court issued a memorandum opinion and order on March 10, 2004 addressing these motions. (See D.I.

¹The jury was not asked to decide whether Smith & Nephew contributed to the infringement or induced the infringement of claims 21 and 42 of the '592 patent with its Saphyre or ElectroBlade products.

483, 484) The court found that the jury based their decisions as to infringement and invalidity upon substantial evidence and upheld the jury verdict. The court granted Arthrocare's motion for a permanent injunction pursuant to the findings of infringement.

Presently before the court are Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction and Smith & Nephew's motion to stay the injunction or, alternatively, to grant a transition period. For the reasons that follow, the court denies the motion for reconsideration, denies the motion to stay in part as to the stay per se, and grants the motion to stay in part to allow for a three month transition period.

II. DISCUSSION

A. Smith & Nephew's Motion for Reconsideration of Orders Granting Arthrocare's Motion for a Permanent Injunction²

"As a general rule, motions for reconsideration should be granted 'sparingly.'" Stafford v. Noramco of Delaware, Inc., 2001 WL 65738, *1 (D. Del. 2001) (quoting Karr v. Castle, 768 F.

²Because the court dismissed Smith & Nephew's antitrust counterclaim, the court concluded that it was not premature to enter a permanent injunction in favor of Arthrocare. (D.I. 483 at 90, n.29) Thus, Smith & Nephew's instant motion is inextricably tied to the motion to dismiss. The court, therefore, necessarily must address its decision to dismiss the antitrust counterclaims in the context of the instant motion for reconsideration.

Supp. 1087, 1090 (D. Del. 1991)). The purpose of granting a motion for reconsideration is to "correct manifest errors of law or fact or to present newly discovered evidence." Harsco Corp. v. Zlotnicky, 176 F.3d 669, 677 (3d Cir. 1999) (citing Keene Corp. v. International Fid. Ins. Co., 561 F. Supp. 656, 665 (N.D. Ill. 1983)). Parties, therefore, should remain mindful that a motion for reconsideration is not merely an opportunity to "accomplish repetition of arguments that were or should have been presented to the court previously." Karr v. Castle, 768 F. Supp. 1087, 1093 (D. Del. 1991) (citing Brambles U.S.A., Inc. v. Blocker, 735 F. Supp. 1239, 1240-41 (D. Del. 1990)). A court should reconsider a prior decision if it overlooked facts or precedent that reasonably would have altered the result. Id. (citing Weissman v. Fruchtmann, 124 F.R.D. 559, 560 (S.D.N.Y. 1989)).

Smith & Nephew complains that the court, in granting Arthrocare's motion to dismiss its antitrust counterclaim, relied on two mistaken assumptions: (1) that Arthrocare's motion to dismiss was unopposed; and (2) that the viability of Smith & Nephew's antitrust counterclaim depends on a showing that the antitrust action was objectively baseless "sham" litigation. Smith & Nephew argues that it did not respond to the motion to dismiss because the court specifically stayed the antitrust counterclaim pending resolution of the patent issues during a teleconference with the parties on June 9, 2003.

As a result, Smith & Nephew asserts that its intent to oppose the motion to dismiss coupled with the court's orders staying the issue presents sufficient grounds for reconsideration.

The court disagrees. As noted above, on November 27, 2002, the court issued a memorandum order staying discovery and trial of Smith & Nephew's antitrust counterclaim. (D.I. 206) The court reviewed this order in deciding the motion to dismiss and concluded that said stay did not impact the motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). Arthrocare filed this motion in lieu of an answer to Smith & Nephew's antitrust counterclaims. As such, the court simply addressed the sufficiency of Smith & Nephew's counterclaim; it did not resolve disputed facts or decide the merits of Smith & Nephew's antitrust case. Therefore, the court acted consistent with its prior rulings.³

More importantly, the court decided said motion based upon the correct law. The court noted in its memorandum opinion that "[t]he Supreme Court has held that Noerr-Pennington immunity does not apply to petitions that are a 'mere sham to cover what is

³Smith & Nephew's reliance on one statement from a June 2003 teleconference is misplaced. The court notes in this regard that the instant docket consists of hundreds of entries, including a dozen transcripts from telephone conferences. The court has had to resolve fifty-one substantive motions in this case, which is only one of sixty-six patent cases on the court's docket. If Smith & Nephew believed that Arthrocare's motion was premature and inconsistent with the court's prior rulings, it should have indicated so in a timely manner.

actually nothing more than an attempt to interfere directly with the business relationships of a competitor.'" (D.I. 481 at 6-7) The court applied this holding and concluded that "the objective threshold for 'sham' litigation is not satisfied and that the Noerr-Pennington doctrine shields Arthrocare from liability for Smith & Nephew's antitrust counterclaims." (Id. at 8) The court is not persuaded that any argument from Smith & Nephew about the basis for its antitrust allegations will change the court's decision. Accordingly, because the court is convinced that it properly decided the motion to dismiss, the court denies Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction.

B. Smith & Nephew's Motion to Stay the Permanent Injunction Or, Alternatively, to Grant a Transition Period

Smith & Nephew seeks a stay of the permanent injunction pending appeal to avoid injustice or, in the alternative, a six to twelve month transition period to allow the medical community to switch to alternative products. A court may stay an injunction pending appeal pursuant to Federal Rule of Civil Procedure 62(c). In exercising its discretion to issue such a stay, the Federal Circuit has indicated that a court must consider four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay;

(3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." Standard Havens Prods. v. Gencor Indus., 897 F.2d 511, 512 (Fed. Cir. 1990) (citations omitted). The Federal Circuit also has opined that each factor need not be given equal weight. Id. at 513. Instead, a court should use a flexible balancing approach.

Applying these considerations to Smith & Nephew's assertion that it is entitled to a stay pending appeal, the court finds that Smith & Nephew has not established any of Standard Havens factors sufficient to warrant a stay. First, there is no convincing evidence that Smith & Nephew's appeal carries a strong likelihood of success on the merits. Smith & Nephew argues that the ultimate validity of the asserted patents is in substantial doubt given that the United States Patent & Trademark Office ("PTO") has granted its requests for reexamination of each of the asserted patents, finding "substantial new questions of patentability." A reexamination proceeding, however, is different from litigation. Indeed, the Federal Circuit has recognized that "litigation and reexamination are distinct proceedings, with distinct parties, purposes, procedures, and outcomes."⁴ Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427 (Fed.

⁴The Federal Circuit explained the distinctions between the two proceedings succinctly as follows:

Before the courts, a patent is presumed valid and the

Cir. 1988) (citing In re Etter, 756 F.2d 852, 857 (Fed. Cir. 1985)). To this end, "[t]he two forums take different approaches in determining invalidity and on the same evidence could quite correctly come to different conclusions. . . . And, if the district court determines a patent is not invalid, the PTO should continue its reexamination because, of course, the two forums have different standards of proof for determining validity." Id. at 1428-29. In light of these differences, the court is not persuaded that the ongoing reexamination proceeding triggers a stay of the injunction. A jury has decided the validity of the patents in suit after careful deliberation following a nine day jury trial. This court reviewed the jury's verdict pursuant to post-trial motions and found that the jury based its decision on substantial evidence. Thus, the court has no reason to believe

party asserting invalidity must prove the facts to establish invalidity of each claim by clear and convincing evidence. . . . In a reexamination proceeding, on the other hand, there is no presumption of validity and the "focus" of the reexamination returns essentially to that present in an initial examination, . . . at which a preponderance of the evidence must show nonpatentability before the PTO may reject the claims of a patent application. . . . The intent underlying reexamination is to 'start over' in the PTO with respect to the limited examination areas involved, and to re-examine the claims, and to examine new or amended claims, as they would have been considered if they had been originally examined in light of all of the prior art of record in the reexamination proceeding.

Id. (citations and quotations omitted).

that Smith & Nephew will be successful on its appeal such that the court presently should issue a stay.

Smith & Nephew also asserts that there are substantial claim construction issues on appeal that will require further action by the court.⁵ Smith & Nephew reminds the court that "the Federal Circuit conducts a de novo review of claim construction, and quite frequently reverses or at least modifies the construction applied by the [d]istrict [c]ourt." (D.I. 487 at 11) Nevertheless, as counsel for Smith & Nephew is aware, the court previously has held that the "possibility of appellate de novo review of its claim construction does not constitute an extraordinary circumstance to merit a stay." Eaton Corp. v. Parker-Hannifin Corp., 292 F. Supp. 2d 555, 582 (D. Del. 2003); see Tristrata Tech., Inc. v. ICN Pharms., Inc., 2004 WL 856595, *2 (D. Del. 2004).

Smith & Nephew further contends that it will appeal the fact that the jury was allowed to decide the validity of the Certificate of Correction for the '882 patent. Smith & Nephew maintains that such procedure was contrary to the steps outlined in Superior Fireplace v. Majestic Prods., 270 F.3d 1358 (Fed. Cir. 2001). Smith & Nephew, therefore, avers that it has a

⁵Smith & Nephew particularly challenges the court's claim construction of the "not in contact" limitation in the '592 patent and the "connector" limitation of the '536 patent.

reasonable likelihood of succeeding on this claim.⁶ This assertion is little more than conclusory attorney argument. Moreover, the court agreed with the jury verdict that the certificate of correction is valid. Therefore, even if it was improper to submit this decision to the jury, the court ultimately decided the very issue at the heart of Smith & Nephew's complaint. Accordingly, the court concludes that the first factor weighs against the issuance of a stay.

Second, Smith & Nephew argues that it will be irreparably harmed if a stay is not granted because it will be unable to recover a position in the market. In this regard, Smith & Nephew claims that its ElectroBlade and Saphyre probes are the result of twenty-seven years and millions of dollars in research and development efforts. This argument is a warmed-over version of Smith & Nephew's prior contentions made in opposition to Arthrocare's motion for a permanent injunction. As the patentee, Arthrocare presumptively has suffered irreparable harm throughout the duration of Smith & Nephew's infringing activities. Smith & Nephew cannot now attempt to turn the table and argue that it will suffer harm for continuing to engage in infringement. Such contention offends the very rights associated with obtaining a patent. Additionally, the only harm that Smith

⁶Absent a finding of validity of the Certificate of Correction, Smith & Nephew would not be liable for infringement of the '882 patent.

& Nephew will suffer with any certainty is the loss of profits from the sale of its ElectroBlade and Saphyre probes.⁷ Smith & Nephew has failed to show that any of its employees will lose their jobs, despite alleging that its employees derive their livelihood from the manufacture and sale of the infringing products. As the court originally stated in deciding the parties' post-trial motions, "one who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 (Fed. Cir. 1986); see also E.I. DuPont De Nemours & Co., v. Phillips Petroleum Co., 659 F. Supp. 92, 94-95 (D. Del. 1987) (stating "the loss of customers or business built upon the sale and use of infringing products does not amount, in the context of a patent infringement suit, to irreparable harm from which [the defendant] should be shielded). The court, consequently, concludes that the second factor weighs against the issuance of a stay.

Third, Smith & Nephew claims that Arthrocare's pattern of licensing demonstrates that monetary damages will adequately compensate Arthrocare for its continued infringement during the

⁷Smith & Nephew reported revenue of almost two billion in 2003. (D.I. 487 at 16 n.5) From the infringing products alone, Smith & Nephew generated six million in sales before trial and approximately 7.5 million since the jury verdict. (See D.I. 418 at 869; D.I. 491 at 18)

appeals process. This argument is unpersuasive. Staying the injunction during the appeals process would essentially allow Smith & Nephew to continue to infringe, thereby further usurping the exclusivity that Arthrocare is entitled to enjoy as a result of its patents. Such exclusivity underlies the patent system in the United States. Moreover, Arthrocare's patent rights are not compromised simply because it opted to license its patents to select competitors. "Once the patentee's patents have been held to be valid and infringed, he should be entitled to the full enjoyment and protection of his patent rights." Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983).

Furthermore, if Smith & Nephew continues to sell its infringing products, Arthrocare likely will lose market share, profits, and goodwill. Smith & Nephew, in fact, has implemented a specific program within its sales force to convert Arthrocare's customers to using Smith & Nephew products. (See D.I. 491, ex. A) The Federal Circuit has observed that "because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole." Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1456-57 (Fed. Cir. 1988). As well, "[i]f monetary relief were the sole relief afforded by the patent statute then injunctions would be unnecessary and infringers could become compulsory licensees for as long as the

litigation lasts." Atlas Powder Co. v. Ireco Chems., 773 F.2d 1230, 1233 (Fed. Cir. 1985). In light of the foregoing, the court concludes that the third factor weighs against the issuance of a stay.

Finally, Smith & Nephew charges that an injunction would adversely affect surgeons and their patients. Smith & Nephew specifically claims that denying a stay will deprive surgeons in the United States of their choice of surgical instruments, especially given that the infringing products offer unique features and medical advantages not available in other products.⁸ Nonetheless, the court does not find a stay warranted simply because the litigation at bar involves medical devices as opposed to some other technology that does not relate to issues of human health.⁹ While the court appreciates that select surgeons like Dr. Roy A. Majors and Dr. Gary S. Fanton, both of

⁸The ElectroBlade combines a mechanical shaver with an RF coagulation device, thereby allowing surgeons to resect soft tissue, coagulate bleeders, and continue resecting with a single instrument. The Saphyre utilizes a CoolBack feature, which prevents contact between the return electrode and non-target tissue.

⁹The court notes that Smith & Nephew attempts to mislead it into believing such to be the case in the District of Delaware by its characterization of C.R. Bard, Inc. v. Medtronic, Inc., 1999 WL 458305 (D. Del. 1999). Smith & Nephew suggests that the court stayed an injunction pending appeal because the technology involved arterial filters. (See D.I. 487 at 17) In truth, the court stayed the injunction because the jury's verdict rested on a close question of law concerning the doctrine of equivalents. Id. at 15.

whom submitted declarations on behalf of Smith & Nephew, rely on the unique features offered by the ElectroBlade and Saphyre products, the court finds that reasonable alternative probes exist in the market. As mentioned previously in the court's post-trial memorandum opinion, ArthroCare, Mitek, and Stryker offer probes for use in arthroscopic surgery. The court has no reason to believe that these probes will pose medical risks to patients. Surgeons in the United States, therefore, may utilize them in place of the ElectroBlade and Saphyre probes, albeit after instruction and training. Consequently, the court finds that the fourth factor weighs against the issuance of a stay.

In sum, since all four of the Stanford Havens factors weigh against the issuance of a stay, the court concludes that a stay pending appeal is not justified. Accordingly, the court denies Smith & Nephew's motion to stay the injunction.

With regard to a transition period, the court disagrees with Smith & Nephew that the medical community may need six to twelve months to effect an efficient and orderly transition. The jury returned its verdict of infringement on May 12, 2003. Smith & Nephew, nevertheless, continued to sell and presently still sells the ElectroBlade and Saphyre probes.¹⁰

¹⁰Smith & Nephew stated that in the past year surgeons treated 50,000 patients at 900 hospitals and surgery centers and 200 sales representative spent approximately \$1,100,000 training surgeons and hospital staff to uses its probes. (See D.I. 487 at 17)

Smith & Nephew could have utilized the time between the jury verdict and present to implement the transition it now requests. What is more, a lengthy transition of six to twelve months will cause further irreparable harm to Arthrocare. Notwithstanding this, the court finds that a short transition period of three months is appropriate to allow Smith & Nephew time to alert surgeons not to utilize its probes. This period will also permit the surgeons who rely on Smith & Nephew products to receive instruction and switch to alternative probes. During this time, Smith & Nephew shall not sell any additional infringing probes from its inventory. If Arthrocare becomes aware of such sales by Smith & Nephew, then Arthrocare may immediately notify the court.

III. CONCLUSION

The court denies Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction. The court also denies Smith & Nephew's motion to stay in part as to the stay per se and grants said motion in part to allow for a three month transition period. An order shall issue.

(508)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

O R D E R

At Wilmington this ^{31st} day of April, 2004, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction (D.I. 433) is denied.

2. Smith & Nephew's motion to stay or alternatively, to grant a transition period (D.I. 486) is denied in part as to the stay and granted in part to allow for a three month transition period.


United States District Judge

(529)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

REVISED ORDER*

At Wilmington this ¹⁴ day of April, 2004, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction (D.I. 488*) is denied.
2. Smith & Nephew's motion to stay or alternatively, to grant a transition period (D.I. 486) is denied in part as to the stay and granted in part to allow for a three month transition period.

John L. Robinson
United States District Judge

(502)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

O R D E R

At Wilmington this 9th day of June, 2004, having conferred with counsel and having reviewed the papers submitted by the parties;¹

IT IS ORDERED that, with respect to the U.S. Patent No. 5,697,536 ("the '536 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from:

(a) directly infringing claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by making, using, offering to sell, or selling in the United States, or importing into the United States, the Saphyre,² ElectroBlade, or Control RF

¹Arthrocare's motion for entry of a permanent injunction (D.I. 485) is granted, and Smith & Nephew's motion to delay entry of injunction pending consideration of motion to stay injunction in Federal Circuit (D.I. 511) is denied as moot.

²When the court refers to the Saphyre products listed on Exhibit A herein, the court intends to include both the suction and non-suction models, unless otherwise specified.

products listed on Exhibit A attached hereto; (b) inducing the infringement of claims 46, 47, and 48 of the '536 patent until the expiration of the '536 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A ; and (c) contributing to the infringement of claims 46, 47, and 48 of the '536 patent until the expiration of the '536 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 5,697,882 ("the '882 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from

inducing the infringement of claim 54 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the suction models of Saphyre products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 17 and 54 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

5. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from

contributing to the infringement of claim 54 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the suction models of the Saphyre products listed on Exhibit A.

6. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 17 and 54 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 6,224,592 ("the '592 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents,

servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 21 and 42 of United States the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 21 and 42 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that:


1. Defendant Smith & Nephew retrieve from all persons and

entities, including sales representatives, distributors, executives, doctors, and hospitals, all Saphyre, ElectroBlade, and Control RF products listed in Exhibit A for which title has not passed from Smith & Nephew, Inc..

2. Defendant Smith & Nephew provide a copy of this order to each of its sales representatives, distribution executives, and other distributors for the Saphyre, ElectroBlade, and Control RF products listed in Exhibit A, whether or not such persons are employees of Smith & Nephew, Inc..

3. Defendant Smith & Nephew shall have a transition period from the date of this order until July 27, 2004³ to allow time for defendant Smith & Nephew to alert surgeons not to utilize the Saphyre, ElectroBlade, and Control RF probes listed on Exhibit A and for surgeons to receive instruction on alternative, non-infringing products.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined committing any of the acts enumerated herein during this transition period.


United States District Judge

³The court granted Smith & Nephew a three month transition period commencing on April 27, 2004. (See D.I. 508) This transition period concludes on July 27, 2004.

Exhibit A

The Infringing Products

I. Saphyre Products

Saphyre 90-degree, 3 mm Bipolar Ablation Probe, Integrated Cable,
REF 925001 / 7209686

Saphyre 90-degree, 3 mm Suction Bipolar Ablation Probe,
Integrated Cable, REF 925011 / 7209683

Saphyre 60-degree, 3 mm Bipolar Ablation Probe, Integrated Cable,
REF 925003 / 7209685

Saphyre 60-degree, 3 mm Suction Bipolar Ablation Probe,
Integrated Cable, REF 925013 / 7209682

Saphyre 90-degree HP Ablator, REF 7209684

Saphyre 90-degree HP Ablator with suction, REF 7209681

Pro-Saphyre 60-degree Small Joint with Suction, Oratec No. 925016

Pro-Saphyre 60-degree Small Joint, Oratec No. 925026

Saphyre II 90-degree HP with Suction, REF 7210112

Saphyre II 90-degree with Suction, REF 7210111

Saphyre II 60-degree with Suction, REF 7210113

Saphyre II 40-degree curved with Suction, REF 7210185

II. ElectroBlade Products

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius
Blade, REF 7205961

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite, REF
7209700

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Full Radius
Vulcan Plug-in, REF 7205962

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Elite Vulcan
Plug-in, REF 7209982

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius
Blade Vulcan Plug-in, REF 7209855

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite Vulcan
Plug-in, REF 7209983

III. Control RF Products

Dyonics Series 7000 RF Arthroscopic Probe, Type RS, REF 7205956

Dyonics Series 7000 RF Arthroscopic Probe, Type RSX, REF 7205957

Dyonics Series 7000 RF Arthroscopic Probe, Type RE, REF 7209034

Dyonics Series 7000 RF Arthroscopic Probe, Type REX, REF 7209035

Dyonics Series 7000 RF Arthroscopic Probe, Type AP, REF 7209036

Dyonics Series 7000 RF Arthroscopic Probe, Type APX, REF 7209037

Dyonics Series 7000 RF Arthroscopic Probe, Type MR, REF 7209038

Dyonics Series 7000 RF Arthroscopic Probe, Type MRX, REF 7209039

Dyonics Control RF Generator Adaptor, REF 7207908

(524)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

AMENDED ORDER

At Wilmington this ¹⁴ day of June, 2004, having conferred with counsel and having reviewed the papers submitted by the parties;¹

Upon entry, this Amended Order shall replace and supercede the Order entered by this Court on June 9, 2004 (D.I. 522):

IT IS ORDERED that, with respect to the U.S. Patent No. 5,697,536 ("the '536 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from:

(a) directly infringing claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by making, using, offering to sell, or selling in the United States, or importing

¹Arthrocare's motion for entry of a permanent injunction (D.I. 485) is granted, and Smith & Nephew's motion to delay entry of injunction pending consideration of motion to stay injunction in Federal Circuit (D.I. 511) is denied as moot.

into the United States, the Saphyre,² ElectroBlade, or Control RF products listed on Exhibit A attached hereto; (b) inducing the infringement of claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A ; and (c) contributing to the infringement of claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 5,697,882 ("the '882 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

²When the court refers to the Saphyre products listed on Exhibit A herein, the court intends to include both the suction and non-suction models, unless otherwise specified.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13, 17, and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the suction models of Saphyre products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 17 and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the non-suction models of the Saphyre products.

listed on Exhibit A.

5. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13, 17, and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the suction models of the Saphyre products listed on Exhibit A.

6. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 17 and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 6,224,592 ("the '592 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by

inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 21 and 42 of the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 21 and 42 of the '592

patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that:

1. Defendant Smith & Nephew retrieve from all persons and entities, including sales representatives, distributors, executives, doctors, and hospitals, all Saphyre, ElectroBlade, and Control RF products listed in Exhibit A for which title has not passed from Smith & Nephew, Inc.

2. Defendant Smith & Nephew provide a copy of this order to each of its sales representatives, distribution executives, and other distributors for the Saphyre, ElectroBlade, and Control RF products listed in Exhibit A, whether or not such persons are employees of Smith & Nephew, Inc.

3. Defendant Smith & Nephew shall have a transition period from the date of this order until July 27, 2004³ to allow time for defendant Smith & Nephew to alert surgeons not to utilize the Saphyre, ElectroBlade, and Control RF probes listed on Exhibit A and for surgeons to receive instruction on alternative, non-infringing products.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active

³The court granted Smith & Nephew a three month transition period commencing on April 27, 2004. (See D.I. 508) This transition period concludes on July 27, 2004.

concert or participation with any of them, are enjoined from committing any of the acts enumerated herein during this transition period..

W. L. Roberson
United States District Judge

Exhibit A

The Infringing Products

I. Saphyre Products

Saphyre 90-degree, 3 mm Bipolar Ablation Probe, Integrated Cable,
REF 925001 / 7209686

Saphyre 90-degree, 3 mm Suction Bipolar Ablation Probe,
Integrated Cable, REF 925011 / 7209683

Saphyre 60-degree, 3 mm Bipolar Ablation Probe, Integrated Cable,
REF 925003 / 7209685

Saphyre 60-degree, 3 mm Suction Bipolar Ablation Probe,
Integrated Cable, REF 925013 / 7209682

Saphyre 90-degree HP Ablator, REF 7209684

Saphyre 90-degree HP Ablator with suction, REF 7209681

Pro-Saphyre 60-degree Small Joint with Suction, Oratec No. 925016

Pro-Saphyre 60-degree Small Joint, Oratec No. 925026

Saphyre II 90-degree HP with Suction, REF 7210112

Saphyre II 90-degree with Suction, REF 7210111

Saphyre II 60-degree with Suction, REF 7210113

Saphyre II 40-degree curved with Suction, REF 7210185

II. ElectroBlade Products

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius
Blade, REF 7205961

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite, REF
7209700

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Full Radius
Vulcan Plug-in, REF 7205962

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Elite Vulcan
Plug-in, REF 7209982

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius
Blade Vulcan Plug-in, REF 7209855

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite Vulcan
Plug-in, REF 7209983

III. Control RF Products

Dyonics Series 7000 RF Arthroscopic Probe, Type RS, REF 7205956

Dyonics Series 7000 RF Arthroscopic Probe, Type RSX, REF 7205957

Dyonics Series 7000 RF Arthroscopic Probe, Type RE, REF 7209034

Dyonics Series 7000 RF Arthroscopic Probe, Type REX, REF 7209035

Dyonics Series 7000 RF Arthroscopic Probe, Type AP, REF 7209036

Dyonics Series 7000 RF Arthroscopic Probe, Type APX, REF 7209037

Dyonics Series 7000 RF Arthroscopic Probe, Type MR, REF 7209038

Dyonics Series 7000 RF Arthroscopic Probe, Type MRX, REF 7209039

Dyonics Control RF Generator Adaptor, REF 7207908

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US District Court Civil Docket

US District Court for the District of Delaware
(Wilmington)

1:01cv504

Arthrocare Corp v. Smith & Nephew Inc, et al

This case was retrieved from the court on Tuesday, May 25, 2004

Date Filed: 07/25/2001	Class Code: APPEAL
Assigned To: Judge Sue L Robinson	Closed: No
Referred To:	Statute: 35:271
Nature of suit: Patent (830)	Jury Demand: Both
Cause: Patent Infringement	Demand Amount: \$0
Lead Docket: None	
Other Docket: Dkt # In USDC/N.D.CA : Is C98-00609	
Jurisdiction: Federal Question	

Litigants

Arthrocare Corporation
PLAINTIFF

v.

Smith & Nephew Inc
DEFENDANT

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v.

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Wilmington , DE 19899
USA
(302) 658-9200

Date	#	Proceeding Text
07/25/2001	<u>1</u>	COMPLAINT filed; Mag consent notice to pltf. FILING FEE \$ 150.00 RECEIPT # 130905 (rc) [Entry date 07/26/01]
07/25/2001	=	DEMAND for jury trial by ArthroCare Corp. (rc) [Entry date 07/26/01]
07/25/2001	=	SUMMONS(ES) issued for Smith & Nephew Inc. (rc) [Entry date 07/26/01]
07/25/2001	<u>2</u>	Report to Commissioner of Patents and Trademarks. Exit original. Re: 5,697,536; 5,697,882, 6,224,592 B1 (rc) [Entry date 07/26/01]
07/25/2001	<u>3</u>	RETURN OF SERVICE executed as to Smith & Nephew Inc. 7/25/01 Answer due on 8/14/01 for Smith & Nephew Inc. (rc) [Entry date 07/26/01]
08/01/2001	<u>4</u>	CASE assigned to Judge Sue L. Robinson . Notice to all parties. (rb)
08/15/2001	<u>5</u>	STIPULATION with proposed order re extending time for deft's to resp. to complaint (lj)
08/17/2001	=	So Ordered granting [5-1] stipulation reset Answer deadline to 9/13/01 for Smith & Nephew Inc. (signed by Judge Sue L. Robinson) Notice to all parties. (rd) [Entry date 08/20/01]
09/05/2001	<u>6</u>	MOTION by ArthroCare Corp. with Proposed Order for Matthew D. Powers and Jared Bobrow of Weil to Appear Pro Hac Vice (rd)
09/07/2001	=	So Ordered granting [6-1] motion for Matthew D. Powers and Jared Bobrow of Weil to Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
09/10/2001	<u>7</u>	MOTION by ArthroCare Corp. to enjoin Second-filed Duplicative litigation Answer Brief due 9/24/01 re: [7-1] motion (rd) [Entry date 09/12/01]
09/10/2001	<u>8</u>	Opening Brief Filed by ArthroCare Corp. [7-1] motion to enjoin Second-filed Duplicative litigation (rd) [Entry date 09/12/01]
09/12/2001	<u>9</u>	Letter to Clerk from K. J. Loudon enclosing Exhibit F to Pltf.'s opening brief in support of motion to enjoin filed on 9/10/01. (rd) [Entry date 09/14/01]
09/13/2001	<u>10</u>	ANSWER to complaint and COUNTERCLAIM by Smith & Nephew Inc. (Attorney); jury demand against ArthroCare Corp. (rd) [Entry date 09/14/01]
09/13/2001	<u>11</u>	MOTION by Smith & Nephew Inc. to Change Venue Pursuant to 28 U.S.C. Section 1404(a) Answer Brief due 9/27/01 re: [11-1] motion (rd) [Entry date 09/14/01]
09/13/2001	<u>12</u>	Opening Brief Filed by Smith & Nephew Inc. [11-1] motion to Change Venue Pursuant to 28 U.S.C. Section 1404(a) (rd) [Entry date 09/14/01]
09/13/2001	<u>13</u>	Declaration of Keith A. Walter, Jr. in support of DI 11. (rd) [Entry date 09/14/01]
09/13/2001	<u>14</u>	Declaration of Joel Petrow, Esq. in support of DI 11. (rd) [Entry date 09/14/01]
09/13/2001	<u>15</u>	Notice of Deficiency from the court to defendant Smith & Nephew Inc. re no original signature on DI 14. (rd) [Entry date 09/14/01]
09/17/2001	<u>16</u>	CERTIFICATE OF SERVICE by ArthroCare Corp. re (1) 1st set of req. for prod. of doc. and things and (2) 1st set of interrog. (rd) [Entry date 09/20/01]
09/20/2001	<u>17</u>	Declaration of Joel Petrow, Esq. in support of Deft.'s Motion to Transfer Venue. (rd) [Entry date 09/21/01]
09/24/2001	<u>19</u>	Answer Brief Filed by Smith & Nephew Inc. [7-1] motion to enjoin Second-filed Duplicative litigation - Reply Brief due 10/1/01 (rd) [Entry date 09/26/01]
09/25/2001	<u>18</u>	ORDER, set Tele-Scheduling Conference for 8:30 10/30/01 (signed by Judge Sue L. Robinson) copies to: cnsl. (rd) [Entry date 09/26/01]
09/26/2001	<u>20</u>	ANSWER by ArthroCare Corp. to [10-2] counter claim (rd) [Entry date 09/28/01]

- 09/27/2001 21 STIPULATION to extend time for plff. to answer deft.'s motion to transfer and to file reply brief to its motion to enjoin; with proposed order (rd) [Entry date 09/28/01]
- 09/28/2001 = So Ordered granting [21-1] stipulation reset Answer Brief Deadline to 10/3/01 re: [11-1] motion to Change Venue Pursuant to 28 U.S.C. Section 1404(a), and reset Reply Brief Deadline to 10/3/01 re: [7-1] motion to enjoin Second-filed Duplicative litigation (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 10/01/2001 22 Letter to Judge Robinson from W. Marsden, Jr. advising Court that deft. is withdrawing its motion to transfer, (DI #11), based on recent developments in parallel litigation in California. (rd) [Entry date 10/15/01]
- 10/01/2001 = WITHDRAWAL of [11-1] motion to Change Venue Pursuant to 28 U.S.C. Section 1404(a) per DI 22. (rd) [Entry date 10/15/01]
- 10/12/2001 23 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re (1) 1st set of Interrog. (nos. 1-14) and (2) 1st req. for prod. of doc. and things (rd) [Entry date 10/16/01]
- 10/15/2001 24 STIPULATION re extension of time for filing resp. to discovery requests; with proposed order (rd) [Entry date 10/16/01]
- 10/17/2001 = So Ordered granting [24-1] stipulation re extension of time for responses to discovery requests. (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 10/26/2001 25 CERTIFICATE OF SERVICE by ArthroCare Corp. re Initial Disclosures (rd)
- 10/26/2001 26 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re Initial Disclosures (rd)
- 10/29/2001 27 Letter to Judge Robinson from J. Blumenfeld enclosing proposed sched. order for discussion at telecnf. on 10/30/01. (rd)
- 10/30/2001 = Scheduling conference held via telecnf.; Judge Robinson presiding; no crt. rpt. present. (rd)
- 10/30/2001 28 MOTION by Smith & Nephew Inc. with Proposed Order for Kurtis D. MacFerrin to Appear Pro Hac Vice (rd)
- 10/31/2001 = So Ordered granting [28-1] motion for Kurtis D. MacFerrin to Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 11/09/2001 29 Letter to Judge Robinson from J. Blumenfeld enclosing proposed scheduling order (rd) [Entry date 11/13/01]
- 11/09/2001 30 Proposed Scheduling Order filed by ArthroCare Corp. (rd) [Entry date 11/13/01]
- 11/14/2001 = So Ordered [30-1] proposed order set Scheduling Order Deadlines; joining of parties, amended pleadings on 3/8/02 Discovery deadline on 11/22/02 Deadline for filing dispositive motions by 12/20/02, answering briefs due 1/31/03, reply briefs due 2/14/03; Pretrial conference by 4:30 4/15/03; Jury Trial Date Deadline 9:30 4/28/03, set In-person Discovery Conference for 4:30 3/5/02, and set Motion Filing deadline to 4/1/03 for motions in limine; responses due 4/8/03, set Notice of Compliance deadline to 12/20/02 for filing of Joint Claim Construction Statement; answering briefs due 1/31/03 matter referred to Mag. Judge Thyng for exploring settlement possibility; see order for complete details. (signed by Judge Sue L. Robinson) Notice to all parties. (rd) [Entry date 11/16/01]
- 11/15/2001 32 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re resp. to 1st set of Interrog. (nos. 1-7) and resp. to 1st set of req. for prod. of doc. (nos. 1-54). (rd) [Entry date 11/21/01]
- 11/21/2001 31 MOTION by Smith & Nephew Inc. with Proposed Order for Mark J. Hebert to Appear Pro Hac Vice (rd)
- 11/26/2001 = So Ordered granting [31-1] motion for Mark J. Hebert to Appear Pro Hac Vice

- (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 11/26/2001 33 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re (1) 2nd req. for prod. of doc. an things (nos. 94-94); and (2) 2nd set of interrog. (nos. 15-16). (rd) [Entry date 11/27/01]
- 11/30/2001 34 MOTION by ArthroCare Corp. with Proposed Order for Perry Clark to Appear Pro Hac Vice (rd)
- 12/03/2001 = So Ordered granting [34-1] motion for Perry Clark to Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 12/20/2001 35 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re Suppl. resp. to pltf.'s interrog. (nos. 4 & 5). (rd)
- 12/27/2001 36 CERTIFICATE OF SERVICE by ArthroCare Corp. re (1) resp. and obj. to deflt.'s 2nd set of req. for prod. of doc. and things (nos. 94-95); and (2) obj. and resp. to deflt.'s 2nd set of interrog. (nos. 15-16). (rd) [Entry date 12/28/01]
- 02/19/2002 = Deadline updated; set Telephone Conference for 3:00 2/26/02 (rd)
- 02/21/2002 = Deadline updated; reset Telephone Conference for 10:00 2/28/02 re Protective Order (rd)
- 02/26/2002 37 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re (1) 3rd set of interrog. (no. 17 and 18); and (2) 3rd req. for prod. of doc. and things (nos. 96-97). (rd)
- 02/27/2002 38 Letter to Judge Robinson from K. Walter, Jr. enclosing proposed protective order for telecnf. (rd) [Entry date 02/28/02]
- 02/27/2002 39 Proposed PROTECTIVE Order filed by Smith & Nephew Inc. (rd) [Entry date 02/28/02]
- 02/28/2002 = Tele-conference held re protective order; Judge Robinson presiding; crt. rptr. B. Gaffigan present. (rd)
- 02/28/2002 42 Steno Notes for 2/28/02 telecnf.; Judge Robinson presiding; crt. rptr. B. Gaffigan present. (rd) [Entry date 03/01/02]
- 03/01/2002 40 STIPULATED PROTECTIVE ORDER; with proposed order (rd)
- 03/01/2002 41 TRANSCRIPT filed [0-0] telephone conference for dates of 2/28/02; Judge Robinson presiding; crt. rptr. B. Gaffigan present. (rd)
- 03/04/2002 = So Ordered granting [40-1] stipulated Protective Order (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 03/05/2002 43 Letter to Judge Robinson from J. Blumenfeld listing items to be raised at discovery status conf. (rd)
- 03/05/2002 44 Letter to Judge Robinson from W. Marsden, Jr. listing proposed agenda for discovery issues to be addressed at disc. status conf. (rd)
- 03/05/2002 = Discovery hearing held in person; Judge Robinson presiding; crt. rptr. K. Maurer present. (rd) [Entry date 03/06/02]
- 03/08/2002 45 MOTION by Smith & Nephew Inc. with Proposed Order for Leave to File Amended Answer & Counterclaim Answer Brief due 3/22/02 re: [45-1] motion (rd) [Entry date 03/11/02]
- 03/08/2002 46 Opening Brief Filed by Smith & Nephew Inc. [45-1] motion for Leave to File Amended Answer & Counterclaim (rd) [Entry date 03/11/02]
- 03/08/2002 47 Letter to Judge Robinson from W. Marsden responding to Court's invitation at the 3/5/02 disc. conf. to provide authority supporting Smith & Nephew's patent misuse defense and discovery sought to develop additional facts to support that defense. (rd) [Entry date 03/11/02]
- 03/08/2002 48 Letter to Judge Robinson from J. Blumenfeld re Smith & Nephew's interrog. nos. 15 and 16, which seek pltf.'s contentions re correctness of Judge Orrick's prelim. inj. decision. (rd) [Entry date 03/11/02]
- 03/11/2002 49 TRANSCRIPT filed [0-0] discovery hearing for dates of 3/5/02; Judge

- Robinson presiding; crt. rpt. K. Maurer present. (rd)
- 03/11/2002 50 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re 4th set of interrog. to pltf. (nos. 19-23). (rd)
- 03/13/2002 51 Steno Notes for 3/5/02 re Discovery Conference; Judge Robinson presiding; crt. rpt. K. Maurer present. (rd)
- 03/13/2002 52 Letter to Judge Robinson from J. Blumenfeld responding to def't's letter of 3/8/02 re party asserting a patent after denial of its prel. injun. motion. (rd)
- 03/21/2002 53 ORDER denying [47-1] denying [48-1] requests that the court order pltf. to answer interrog. numbered 15 and 16 for reasons stated in this order (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 03/22/2002 54 STIPULATION to extend time for pltf. to file answering brief and for def't. to file reply brief to DI#45; with proposed order (rd) [Entry date 03/26/02]
- 03/25/2002 55 Answer Brief Filed by ArthroCare Corp. [45-1] motion for Leave to File Amended Answer & Counterclaim - Reply Brief due 4/1/02 (rd) [Entry date 03/26/02]
- 03/26/2002 56 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re (1) suppl. resp. to 1st set of interrog. (nos. 2 & 6); and (2) 1st suppl. Rule 26(a)(1) Initial Disclosure. (rd)
- 03/27/2002 = So Ordered granting [54-1] stipulation reset Answer Brief Deadline to 3/25/02 re: [45-1] motion for Leave to File Amended Answer & Counterclaim, reset Reply Brief Deadline to 4/2/02 re: [45-1] motion for Leave to File Amended Answer & Counterclaim (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 03/27/2002 57 NOTICE by ArthroCare Corp. to take deposition of Smith & Nephew, Inc. on 4/11/02 (rd) [Entry date 04/03/02]
- 03/28/2002 58 CERTIFICATE OF SERVICE by ArthroCare Corp. re (1) resp. and obj. to 3rd set of req. for prod. of doc. and things (nos. 96-97); and Obj. and resp. to 3rd set of interrog. (nos. 17-18). (rd) [Entry date 04/03/02]
- 03/28/2002 = Return of discovery filed by Pltf. with copy of Local Rule 5.4; only a ntc. of discovery should be filed with the court in this action. (rd) [Entry date 04/03/02]
- 03/29/2002 59 STIPULATION to extend time for def't. to file reply brief to motion to amd. (DI#45); with proposed order (rd) [Entry date 04/03/02]
- 04/01/2002 60 SEALED Letter to Judge Robinson from K. Walter, Jr. (rd) [Entry date 04/03/02]
- 04/03/2002 = So Ordered granting [59-1] stipulation reset Reply Brief Deadline to 4/9/02 re: [45-1] motion for Leave to File Amended Answer & Counterclaim (signed by Judge Sue L. Robinson) Notice to all parties. (rd) [Entry date 04/04/02]
- 04/03/2002 61 SEALED Letter to Judge Robinson from J. Blumenfeld. (rd) [Entry date 04/05/02]
- 04/04/2002 62 MOTION by Smith & Nephew Inc. with Proposed Order for Reargument of [53-1] order Answer Brief due 4/18/02 re: [62-1] motion (rd) [Entry date 04/05/02]
- 04/05/2002 63 Declaration of Keith A. Walter in support of DI#62. (rd)
- 04/09/2002 = Deadline updated; set Telephone Conference for 4:30 4/10/02 (rd)
- 04/09/2002 64 CERTIFICATE OF SERVICE by ArthroCare Corp. re Obj. and Resp. to 4th set of interrog. (nos. 19-23). (rd)
- 04/09/2002 65 Reply Brief Filed by Smith & Nephew Inc. [45-1] motion for Leave to File Amended Answer & Counterclaim (rd) [Entry date 04/10/02]
- 04/09/2002 66 SEALED Letter to Judge Robinson from W. Marsden, Jr. (rd) [Entry date 04/10/02]

- 04/10/2002 = Tele-conference held; Judge Robinson presiding; crt. rpt. B. Gaffigan present; re DI#60 and 61. (rd) [Entry date 04/11/02]
- 04/11/2002 67 Steno Notes for 4/10/02; Judge Robinson presiding; crt. rpt. B. Gaffigan. (rd)
- 04/11/2002 68 TRANSCRIPT filed [0-0] telephone conference for dates of 4/10/02; Judge Robinson presiding; crt. rpt. B. Gaffigan present. (rd) [Entry date 04/15/02]
- 04/16/2002 69 STIPULATION to extend time for pltf. to respond to DI#62; with proposed order (rd) [Entry date 04/17/02]
- 04/16/2002 70 Objections by Smith & Nephew Inc. to [57-1] deposition notice (rd) [Entry date 04/17/02]
- 04/18/2002 = So Ordered granting [69-1] stipulation reset Answer Brief Deadline to 4/26/02 re: [62-1] motion for Reargument of [53-1] order (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 04/24/2002 71 NOTICE by Smith & Nephew Inc. to take deposition of John R. Tighe on 5/13/02 (rd) [Entry date 04/25/02]
- 04/24/2002 72 NOTICE by Smith & Nephew Inc. to take deposition of Christine Hanni on 5/14/02 (rd) [Entry date 04/25/02]
- 04/24/2002 73 NOTICE by Smith & Nephew Inc. to take deposition of John Raffle on 5/8/02 (rd) [Entry date 04/25/02]
- 04/24/2002 74 NOTICE by Smith & Nephew Inc. to take deposition of Hira V. Thapliyal on 5/6/02 (rd) [Entry date 04/25/02]
- 04/24/2002 75 NOTICE by Smith & Nephew Inc. to take deposition of Michael A. Baker on 5/10/02 (rd) [Entry date 04/25/02]
- 04/26/2002 76 Answer Brief Filed by ArthroCare Corp. [62-1] motion for Reargument of [53-1] order - Reply Brief due 5/3/02 (rd) [Entry date 04/29/02]
- 05/01/2002 77 NOTICE by Smith & Nephew Inc. to take deposition of Jack C. Cordes on 5/20/02 (rd) [Entry date 05/02/02]
- 05/01/2002 78 NOTICE by Smith & Nephew Inc. to take deposition of Phillip E. Eggers on 5/21/02 (rd) [Entry date 05/02/02]
- 05/01/2002 79 NOTICE by Smith & Nephew Inc. to take deposition of James M. Heslin on 5/16/02 (rd) [Entry date 05/02/02]
- 05/01/2002 80 NOTICE by Smith & Nephew Inc. to take deposition of Stryker Corp. on 5/21/02 (rd) [Entry date 05/02/02]
- 05/01/2002 81 NOTICE by Smith & Nephew Inc. to take deposition of Ethicon, Inc. on 5/20/02 (rd) [Entry date 05/02/02]
- 05/01/2002 82 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re Subpoena to Custodian of Records, Townsend & Townsend. (rd) [Entry date 05/02/02]
- 05/01/2002 83 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re Subpoena for Custodian of Records, Eggers & Associates, Inc. (rd) [Entry date 05/02/02]
- 05/01/2002 84 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re Subpoena to Custodian of Records, Cordes Engineering, Inc. (rd) [Entry date 05/02/02]
- 05/02/2002 85 Letter to Judge Robinson from K. Walter, Jr. attaching copy of letter requesting oral argument that was to be filed with court on 5/1/02 but was never filed due to inadvertent vendor error; Oral Argument is req. on defl.'s motion for reargument (DI#62). (rd) [Entry date 05/07/02]
- 05/10/2002 = Deadline updated; set Telephone Conference for 2:00 5/16/02 re Discovery issues. (rd)
- 05/13/2002 86 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re Subpoena for Stryker Corp. (rd) [Entry date 05/14/02]
- 05/13/2002 87 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re Subpoena for Ethicon, Inc. (rd) [Entry date 05/14/02]

- 05/13/2002 88 Amended NOTICE by Smith & Nephew Inc. to take deposition of Stryker Corp. on 5/21/02 (rd) [Entry date 05/14/02]
- 05/13/2002 89 Amended NOTICE by Smith & Nephew Inc. to take deposition of Ethicon, Inc. on 5/20/02 (rd) [Entry date 05/14/02]
- 05/16/2002 90 Letter to Judge Robinson from W. Marsden, Jr. re today's telecnf. with the court; and enclosing proposed amended scheduling order. (rd)
- 05/16/2002 91 NOTICE by Smith & Nephew Inc. to take deposition of Hira V. Thapliyal on 6/12/02 (rd) [Entry date 05/17/02]
- 05/16/2002 = Tele-conference held re Discovery issues; Judge Robinson presiding; crt. rpt. B. Gaffigan present. (rd) [Entry date 05/17/02]
- 05/17/2002 = Deadline updated; set Discovery Hearing for 4:30 8/19/02 set during discovery telecnf. on 5/16/02 (rd)
- 05/17/2002 92 TRANSCRIPT filed [0-0] telephone conference for dates of 5/16/02; Judge Robinson presiding; crt. rpt. B. Gaffigan present. (rd)
- 05/20/2002 93 Steno Notes for 5/16/02; Judge Robinson presiding; crt. rpt. B. Gaffigan present. (rd) [Entry date 05/21/02]
- 05/29/2002 94 CERTIFICATE OF SERVICE by ArthroCare Corp. re (1) 2nd set of Interrog. and (2) 2nd set of req. for prod. of doc. and things. (rd) [Entry date 05/30/02]
- 05/29/2002 95 SEALED Letter to Judge Robinson from J. Blumenfeld dated 5/29/02. (rd) [Entry date 05/30/02]
- 05/30/2002 96 Letter to Judge Robinson from W. Marsden, Jr., advising court of status of case and requesting that the stay in the discovery related to the Control RF product continue while parties continue their nego. (rd) [Entry date 05/31/02]
- 06/07/2002 = Deadline updated; set Telephone Conference for 2:00 6/11/02 (rd)
- 06/11/2002 97 Letter to Judge Robinson from J. Blumenfeld re agenda for 6/11/02 telecnf. (rd)
- 06/11/2002 = Tele-conference held; Judge Robinson presiding; crt. rpt. V. Gunning present. (rd) [Entry date 06/13/02]
- 06/11/2002 98 Letter to Judge Robinson from W. Marsden, Jr. responding to Mr. Blumenfeld's letter of 5/29/02. (rd) [Entry date 06/13/02]
- 06/12/2002 99 Letter to Judge Robinson from J. Blumenfeld enclosing a revised proposed scheduling order. (rd) [Entry date 06/13/02]
- 06/12/2002 100 Proposed Revised Scheduling Order filed by ArthroCare Corp. (rd) [Entry date 06/13/02]
- 06/13/2002 = Deadline updated; set Discovery Hearing for 3:00 7/23/02 (rd)
- 06/17/2002 = So Ordered [100-1] proposed order reset Scheduling Order Deadlines: Discovery deadline on 12/16/02 Deadline for filing dispositive motions by 1/3/03; answers due 1/17/03; and reply briefs due 1/24/03, and reset Notice of Compliance deadline to 1/3/03 for parties to file opening claim construction briefs and Joint Claim Construction Statement; on 1/17/03 parties shall file answering claim const. briefs (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 06/28/2002 101 TRANSCRIPT filed [0-0] telephone conference for dates of 06/11/02; Judge Robinson presiding; Crt Rptr V. Gunning present. (rd) [Entry date 07/02/02]
- 07/01/2002 102 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re (1) Resp. to modified 1st set of interrog (Nos.1-7) and (2) Resp. to modified 1st set of req for prod of docs (nos. 1-54) (rd) [Entry date 07/02/02]
- 07/02/2002 103 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re (1) Resp to 2nd set of interrogs (Nos. 8-13) and (2) Resp to 2nd set of req. for prod. of docs (Nos. 55-74) (rd)
- 07/23/2002 104 Letter to Judge Robinson from W. Marsden, Jr. re topics for status conference

- on 7/23/02 (rd)
- 07/23/2002 105 Letter to Judge Robinson from J. Blumenfeld re matters for the agenda for the conference on 7/23/02 (rd)
- 07/23/2002 = Discovery hearing held Judge Robinson presiding; Crt rpt B. Gaffigan present (rd) [Entry date 07/24/02]
- 07/23/2002 106 Steno Notes for 7/23/02; Discovery hearing; Crt Rptr B. Gaffigan (rd) [Entry date 07/24/02]
- 07/24/2002 107 MOTION by Smith & Nephew Inc. with Proposed Order to Bifurcate Willfulness and Damages, and to Stay Discovery Answer Brief due 8/7/02 re: [107-1] motion, Answer Brief due 8/7/02 re: [107-2] motion (rd)
- 07/24/2002 108 Opening Brief Filed by Smith & Nephew Inc. [107-1] motion to Bifurcate Willfulness and Damages, [107-2] motion to Stay Discovery (rd)
- 07/24/2002 109 Declaration of William J. Marsden, Jr. in support of DI # 107 (rd)
- 07/25/2002 = Deadline updated; set Telephone Conference for 4:00 8/27/02 (ft)
- 07/25/2002 110 SEALED TRANSCRIPT filed [0-0] discovery hearing for dates of 7/23/02; Judge Robinson Presiding; Crt Rptr: B. Gaffigan (ft) [Entry date 07/26/02] [Edit date 07/26/02]
- 07/31/2002 111 SEALED Second MOTION by Smith & Nephew Inc. for Leave to File amended answer and counterclm Answer Brief due 8/14/02 re: [111-1] motion (ft) [Edit date 07/31/02]
- 07/31/2002 112 SEALED Opening Brief Filed by Smith & Nephew Inc. [111-1] motion for Leave to File amended answer and counterclm (ft)
- 07/31/2002 113 SEALED Declaration of Keith A. Walter, Jr. in support of Smith & Nephew's second motion for leave to amend answer and counterclm. (ft)
- 08/02/2002 114 STIPULATION to extend time for pltf to serve and file its answering brief in opposition to dft's motion to bifurcate willfulness and damages and stay discovery (DI # 108); with proposed order (ft) [Entry date 08/05/02]
- 08/02/2002 115 Letter to Clerk from W. Marsden, Jr. enclosing a corrected cover page and page 2 to Dft Smith & Nephew's Opening Brief in Support of its Motion to Bifurcate Willfulness and Damages (DI # 108); requests the pages to be substituted; also enclosed is a corrected form of the Motion filed on 7/23/02 (DI # 107) (ft) [Entry date 08/05/02] [Edit date 08/05/02]
- 08/06/2002 = So Ordered granting [114-1] stipulation reset Answer Brief Deadline to 8/9/02 re: [107-1] motion to Bifurcate Willfulness and Damages, 8/9/02 re: [107-2] motion to Stay Discovery (signed by Judge Sue L. Robinson) Notice to all parties. (ft)
- 08/07/2002 116 NOTICE by ArthroCare Corp. to take deposition of Joan McCreary on 8/21/02 (rd) [Entry date 08/09/02]
- 08/07/2002 117 NOTICE by ArthroCare Corp. to take deposition of Karen Drucker on 8/22/02 (rd) [Entry date 08/09/02]
- 08/07/2002 118 3rd NOTICE by ArthroCare Corp. to take deposition of deft. Smith & Nephew on 8/20/02 (rd) [Entry date 08/09/02]
- 08/07/2002 119 2nd NOTICE by ArthroCare Corp. to take deposition of deft. Smith & Nephew on 8/19/02 (rd) [Entry date 08/09/02]
- 08/09/2002 120 SEALED Answer Brief Filed by ArthroCare Corp. [107-1] motion to Bifurcate Willfulness and Damages - Reply Brief due 8/16/02, [107-2] motion to Stay Discovery - Reply Brief due 8/16/02 (rd) [Entry date 08/12/02]
- 08/12/2002 121 STIPULATION to extend time for pltf. to file answering brief to DI#111; with proposed order (rd) [Entry date 08/13/02]
- 08/13/2002 = Deadline updated; set Telephone Conference for 4:30 8/15/02 (rd)
- 08/14/2002 122 Letter to Clerk from J. Blumenfeld enclosing new page 17 to be substituted

- into DI#120. (rd) [Entry date 08/15/02]
- 08/15/2002 == So Ordered granting [121-1] stipulation reset Answer Brief Deadline to 8/16/02 re: [111-1] motion for Leave to File amended answer and counterclm (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 08/15/2002 123 STIPULATION to extend time for deflt. to file reply brief to DI#107; with proposed order (rd)
- 08/15/2002 124 Letter to Judge Robinson from W. Marsden, Jr. identifying issues deflt. shall raise at telecnf. on 8/15/02 (rd)
- 08/15/2002 125 Letter to Judge Robinson from J. Blumenfeld re subjects for today's telecnf. (rd)
- 08/15/2002 == Tele-conference held re discovery; Judge Robinson presiding; crt. rptr. B. Gaffigan. (rd) [Entry date 08/19/02]
- 08/16/2002 == So Ordered granting [123-1] stipulation reset Reply Brief Deadline to 8/21/02 re: [107-1] motion to Bifurcate Willfulness and Damages, 8/21/02 re: [107-2] motion to Stay Discovery (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 08/16/2002 126 Steno Notes for 8/15/02 telecnf.; Judge Robinson presiding; crt. rptr. B. Gaffigan. (rd) [Entry date 08/19/02]
- 08/16/2002 127 TRANSCRIPT filed [0-0] telephone conference for dates of 8/15/02; Judge Robinson presiding; crt. rptr. B. Gaffigan. (rd) [Entry date 08/19/02]
- 08/16/2002 128 SEALED Answer Brief Filed by ArthroCare Corp. [111-1] motion for Leave to File amended answer and counterclm - Reply Brief due 8/23/02 (rd) [Entry date 08/19/02]
- 08/19/2002 129 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re (1) obj. to ntc. of depo. of Karen Drucker; (2) obj. to ntc. of depo. of Joan McCreary; (3) obj. to 2nd ntc. of depo.; and (4) obj. to 3rd ntc. of depo. (rd)
- 08/21/2002 130 SEALED Reply Brief Filed by Smith & Nephew Inc. [107-1] motion to Bifurcate Willfulness and Damages, [107-2] motion to Stay Discovery (ft) [Entry date 08/22/02]
- 08/21/2002 131 SEALED Declaration of Keith A. Walter, Jr. in support of Smith & Nephew's Reply Brief in support of its Motion to Bifurcate Willfulness and Damages (ft) [Entry date 08/22/02] [Edit date 08/22/02]
- 08/22/2002 132 NOTICE by ArthroCare Corp. to take deposition of Todd Plevinsky on 9/17/02; Mike Long on 9/18/02; Dianne DeLucia on 9/25/02; Ron Sparks on 9/26/02; David Balford on 9/27/02; Kara Weldon on 9/25/02; Kate Knudsen on 9/26/02; and Tom Ross on 9/27/02 (ft) [Entry date 08/23/02]
- 08/22/2002 133 Letter to Deputy Clerk Tassone from K. Walter, Jr. re Smith & Nephew's Correct Reply Brief on its Motion to Bifurcate, clarifying the file to have "and Stay Discovery"; various corrections in the brief; requesting substitution of the brief for the one originally filed (D.I. # 130) (ft) [Entry date 08/23/02] [Edit date 08/23/02]
- 08/23/2002 == Deadline updated; set Telephone Conference for 4:00 8/27/02 re status (rd)
- 08/23/2002 134 STIPULATION to extend time for the dft. to file its Reply Brief in support of its Second Motion for Leave to Amend Answer and Counterclaim; with proposed order (ft) [Entry date 08/26/02]
- 08/26/2002 135 SEALED Reply Brief Filed by Smith & Nephew Inc. [111-1] Second motion for Leave to File amended answer and counterclm (ft) [Entry date 08/27/02]
- 08/26/2002 136 Letter to Judge Robinson from K. Walter, Jr. requesting oral argument on Smith & Nephew's Motion to Bifurcate Willfulness and Damages, and Stay Discovery (D.I. 107) (ft) [Entry date 08/27/02]
- 08/26/2002 137 Letter to Judge Robinson from M. Noreika enclosing a copy of an order entered by Judge Sleet in C.A. No. 01-051 GMS; pertinent to D.I. # 45, D.I. # 55, and D.I. # 65 in C.A. No. 01-504-SLR (ft) [Entry date 08/27/02]

- 08/27/2002 = So Ordered granting [134-1] stipulation reset Reply Brief Deadline to 8/26/02 re: [111-1] motion for Leave to File amended answer and counterclm (signed by Judge Sue L. Robinson) Notice to all parties. (ft)
- 08/27/2002 138 Letter to Judge Robinson from K. Walter re agenda for telephone conference at 4:00pm 8/27/02 (ft)
- 08/27/2002 139 Letter to Judge Robinson from K. Walter responding to M. Noreika's letter of 8/26/02 and submitting supplemental authority to the court pursuant to DE Local Rule 7.1.2(c) (ft)
- 08/27/2002 140 Letter to Judge Robinson from M. Noreika re issues that need to be addressed at the teleconference at 4:00 pm 8/27/02; Arthrocare wishes to discuss deposition scheduling and the status of the accused Dyonics Control RF Product (ft)
- 08/27/2002 = Tele-conference held; Judge Robinson presiding; Crt Rptr K. Maurer; re case status (ft) [Entry date 08/28/02]
- 08/29/2002 141 MEMORANDUM ORDER denying [62-1] motion for Reargument of [53-1] order, denying [45-1] motion for Leave to File Amended Answer & Counterclaim (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 08/29/2002 142 Letter to Judge Robinson from K. Walter, Jr. requesting oral argument on Smith & Nephew's Second Motion for Leave to Amend Answer and Counterclaim (DI # 111) (ft) [Entry date 09/03/02]
- 08/29/2002 145 Steno Notes for 8/27/02; notes of telecnf.; Judge Robinson presiding; Crt Rptr K. Maurer (ft) [Entry date 09/06/02]
- 09/03/2002 143 TRANSCRIPT filed [0-0] telephone conference for dates of 8/27/02; Judge Robinson presiding; Crt Rptr K. Maurer (ft) [Entry date 09/04/02]
- 09/04/2002 144 Revised First NOTICE by ArthroCare Corp. to take deposition of Smith & Nephew, Inc. on 9/26/02 (ft) [Entry date 09/06/02]
- 09/06/2002 146 NOTICE by Smith & Nephew Inc. to take deposition of Arthrocare Corp. on 9/24/02 (rd) [Entry date 09/09/02]
- 09/06/2002 147 Letter to Judge Robinson from J. Blumenfeld re pending motion to bifurcate willfulness adn damages (DI#107). (rd) [Entry date 09/09/02]
- 09/10/2002 148 NOTICE by Smith & Nephew Inc. to take deposition of Alan Weinstein on 10/4/02 (ft) [Entry date 09/13/02]
- 09/10/2002 149 NOTICE by Smith & Nephew Inc. to take deposition of James Pacek on 10/2/02 (ft) [Entry date 09/13/02]
- 09/10/2002 150 NOTICE by Smith & Nephew Inc. to take deposition of Jean Woloszko on 10/1/02 (ft) [Entry date 09/13/02]
- 09/10/2002 151 NOTICE by Smith & Nephew Inc. to take deposition of Fernando Sanchez on 10/3/02 (ft) [Entry date 09/13/02]
- 09/10/2002 152 NOTICE by ArthroCare Corp. to take deposition of Mark Kleras, Linda Guthrie, and Duane Marion; date to be provided by Smith & Nephew no later than 9/11/02. (ft) [Entry date 09/13/02]
- 09/10/2002 153 Letter to Judge Robinson from W. Marsden, Jr. responding to D.I. # 147 regarding the timing of Smith & Nephew's election whether or not to rely on the advice of cnsl as a defense to ArthroCare's charge of willful infringement; Arthrocare seeks a ruling in its favor on Smith & Nephew's motion to bifurcate and stay (D.I. #107) without waiting for a decision on the merits of that fully briefed motion (ft) [Entry date 09/13/02]
- 09/11/2002 154 NOTICE by Smith & Nephew Inc. to take deposition of Dennis Denen on 9/20/02 (ft) [Entry date 09/16/02]
- 09/11/2002 155 Objections to pltf Arthrocare Corporation's Revised First Notice of Deposition by Smith & Nephew Inc. (ft) [Entry date 09/16/02]
- 09/12/2002 156 Fourth NOTICE by ArthroCare Corp. to take deposition of Smith & Nephew,

- Inc. on 9/27/02 (ft) [Entry date 09/16/02] [Edit date 09/16/02]
- 09/13/2002 157 NOTICE by Smith & Nephew Inc. to take deposition of Andrew R. Eggers on 10/2/02 (ft) [Entry date 09/16/02]
- 09/13/2002 158 NOTICE by Smith & Nephew Inc. to take deposition of Philip E. Eggers on 9/26/02 (ft) [Entry date 09/16/02]
- 09/13/2002 159 NOTICE by Smith & Nephew Inc. to take deposition of Eric A. Eggers on 10/1/02 (ft) [Entry date 09/16/02]
- 09/13/2002 160 MOTION by Smith & Nephew Inc. with Proposed Order for Reconsideration of a portion of the Court's [141-1] order seeks reargument and reconsideration of paragraphs 2 and 3 of the Order; Answer Brief due 9/27/02 re: [160-1] motion (ft) [Entry date 09/16/02]
- 09/25/2002 161 Letter to Judge Robinson from J. Blumenfeld requesting a teleconf. to resolve disputes in connection with depositions; Fact discovery due to close 10/15/02 (ft) [Entry date 09/26/02]
- 09/26/2002 162 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re subpoena upon Andrew Eggers, Eggers & Associates, Inc., Dublin, OH (ft) [Entry date 09/30/02]
- 09/26/2002 163 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re subpoena upon Eric Eggers, Eggers & Associates, Inc., Dublin, OH (ft) [Entry date 09/30/02]
- 09/26/2002 164 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re subpoena upon Gyrus Medical, Ltd., Maple Grove, MN (ft) [Entry date 09/30/02]
- 09/26/2002 165 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re subpoena upon Philip Eggers, Eggers & Associates, Inc., Dublin, OH (ft) [Entry date 09/30/02]
- 09/26/2002 166 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re subpoena upon the Custodian of Records, Eggers & Associates, Inc., Dublin, OH (ft) [Entry date 09/30/02]
- 09/26/2002 167 Answer Brief Filed by ArthroCare Corp. [160-1] motion for Reconsideration of a portion of the Court's [141-1] order - Reply Brief due 10/3/02 (ft) [Entry date 09/30/02]
- 09/27/2002 168 Letter to Judge Robinson from W. Marsden, Jr. responding to Mr. Blumenfeld's letter of 9/25/02 (DI # 161) requesting a teleconf. to resolve discovery disputes that have arisen; Smith & Nephew agrees that a teleconf. is needed but writes to correct the record with respect to the issues raised by ArthroCare and identify additional discovery issues Smith & Nephew would like the Court to address at the teleconf. (ft) [Entry date 10/01/02]
- 09/27/2002 169 CERTIFICATE OF SERVICE by ArthroCare Corp. re objs to ntc of deposition (ft) [Entry date 10/01/02]
- 09/27/2002 170 Objections to Smith & Nephew's Notice of Deposition under Fed. R. Civ. P. 30 (b)(6) by ArthroCare Corp. (ft) [Entry date 10/01/02]
- 10/03/2002 171 NOTICE by Smith & Nephew Inc. to take deposition of Jack C. Cordes on 10/15/02 (ft) [Entry date 10/07/02]
- 10/03/2002 172 MOTION by Smith & Nephew Inc. with Proposed Order to Strike [167-1] answer brief(Arthrocare Corporation's Opposition to Smith & Nephew's Motion for Reargument) Answer Brief due 10/17/02 re: [172-1] motion (ft) [Entry date 10/07/02]
- 10/07/2002 173 MOTION by Smith & Nephew Inc. with Proposed Order for Thomas M. Johnston, Esq. and Katherine D. Prescott, Esq. to Appear Pro Hac Vice re: [173-1] motion (ft) [Entry date 10/08/02]
- 10/08/2002 = So Ordered granting [173-1] motion for Thomas M. Johnston, Esq. and Katherine D. Prescott, Esq. to Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (rd) [Entry date 10/09/02]
- 10/10/2002 174 Letter to Judge Robinson from K. Walter, Jr. requesting a teleconference with

- the Court to resolve discovery disputes that have arisen in connection with fact discovery and in connection with the parties' letters previously submitted on 9/25/02 and 9/27/02; two general issues which require guidance before the close of fact discovery on 10/15/02; Smith & Nephew requests that the remaining deadlines in this case be extended to allow Smith & Nephew time to gather all the evidence to which it is entitled to prepare for trial (ft)
- 10/11/2002 = Deadline updated; set Telephone Conference for 8:30 10/15/02 (ft)
- 10/15/2002 175 CERTIFICATE OF SERVICE by ArthroCare Corp. re (1) suppl. obj. and resp. to 1st set of interogs. (nos. 4-6); and (2) suppl. obj. and resp. to interogs. (nos. 20 and 21) (rd)
- 10/15/2002 = Tele-conference held; Judge Robinson presiding; crt. rprr. B. Gaffigan present; re discovery issues. (rd)
- 10/15/2002 = Deadline updated; set Discovery Hearing for 9:30 10/30/02 set during telecnf. on 10/15/02 (rd)
- 10/15/2002 176 SEALED Letter from Jack B. Blumenfeld to the Honorable Sue L. Robinson dated 10/15/02 (ft) [Entry date 10/16/02]
- 10/15/2002 177 TRANSCRIPT filed [0-0] telephone conference for dates of 10/15/02; Judge Robinson presiding; Crt Rptr B. Gaffigan (ft) [Entry date 10/17/02]
- 10/16/2002 178 CERTIFICATE OF SERVICE by ArthroCare Corp. re supplemental objs and resp to dft Interrog No. 11 (ft) [Entry date 10/17/02]
- 10/17/2002 179 Steno Notes for 10/15/02 teleconference; Judge Robinson presiding; Crt Rptr B. Gaffigan (ft)
- 10/18/2002 180 Answer Brief Filed by ArthroCare Corp. [172-1] motion to Strike [167-1] answer brief(Arthrocare Corporation's Opposition to Smith & Nephew's Motion for Reargument) - Reply Brief due 10/25/02 (ft)
- 10/29/2002 181 Letter to Judge Robinson from J. Blumenfeld re conference at 9:30 10/30/02; ArthroCare would like to raise the following matters: 1. Status of Depositions; 2. Status of Document Production; 3. Scheduling; 4. Smith & Nephew's Invalidity Contentions; and 5. Reliance on Advice of Counsel (ft)
- 10/30/2002 182 Letter to Judge Robinson from W. Marsden re conference at 9:30 10/30/02; would like to raise the following matters: 1. scheduling; 2. deposition status; 3. document production; 4. contention interrogatories (ft)
- 10/30/2002 = Discovery hearing held; Judge Robinson presiding; Crt Rptr V. Gunning present; re discovery issues; Smith & Nephew ordered to produce certain docs for in camera review; Arthrocare to produce prior art through date of patent issue; Arthrocare must identify docs from Mr. Eggers or allow Smith & Nephew to review Mr. Egger's docs; Arthrocare ordered to search for emails or confirm none exist; all parties to schedule remaining depositions within one week (ft)
- 10/30/2002 = Deadline updated; set Telephone Conference for 12:00 11/7/02 set in court on 10/30/02 (ft)
- 11/06/2002 183 Letter to Judge Robinson from J. Blumenfeld re status of discovery in advance of telephone conference; would like to discuss items 4 and 5 of 10/29/02 letter; attached is a proposed revision to the scheduling order (ft)
- 11/07/2002 184 Letter to Judge Robinson from M. Hebert writing on behalf of Smith & Nephew to list the items would like to raise during 11/7/02 telephone conference (ft)
- 11/07/2002 = Tele-conference held; Judge Robinson presiding; crt. rprr. B. Gaffigan; re discovery issues; set oral argument on "stay" for 11/25/02 at 11:00; parties to file briefs re motion for stay shortly. (rd)
- 11/07/2002 = Deadline updated; set Oral Argument for 11:00 11/25/02 re "stay"; set during telecnf. on 11/7/02 (rd)
- 11/08/2002 185 TRANSCRIPT filed [0-0] telephone conference for dates of 11/7/02; Judge Robinson presiding; Court Rptr B. Gaffigan (ft) [Entry date 11/12/02]
- 11/12/2002 186 Steno Notes for 11/7/02 teleconference; Judge Robinson presiding; Crt Rptr B.

Gaffigan (ft)

- 11/14/2002 187 MOTION by Smith & Nephew Inc. with Proposed Order to Stay these proceedings pending the reexamination of U.S. Patent '536 Answer Brief due 11/29/02 re: [187-1] motion (ft) [Entry date 11/15/02]
- 11/14/2002 188 SEALED Memorandum in Support Filed by Smith & Nephew Inc. [187-1] motion to Stay these proceedings pending the reexamination of U.S. Patent '536 (ft) [Entry date 11/15/02]
- 11/14/2002 189 SEALED Declaration of Mark Hebert in support of DI # 188 (ft) [Entry date 11/15/02] [Edit date 11/15/02]
- 11/15/2002 190 Letter to Judge Robinson from W. Marsden, Jr. enclosing documents and explanation of redactions to the Court for in camera review in accordance with the Court's instructions in the 10/30/02 conference and 11/7/02 teleconference; Smith & Nephew has also provided the declaration of Eugene B. Joswick; the documents and the declaration disclose privileged information and have not been served on ArthroCare; (Sealed enclosures given to Judge Robinson) (ft) [Entry date 11/18/02] [Edit date 11/20/02]
- 11/18/2002 191 Letter to Judge Robinson from K. Walter, Jr. enclosing, in addition to the material Smith & Nephew submitted on 11/15/02 for in camera review, copies of SN 20822 in redacted and unredacted form and an explanation for the redaction attached as Exhibit A; material was inadvertently omitted from the binder that Smith & Nephew submitted on 11/15/02 (Sealed enclosures given to Judge Robinson) (ft) [Edit date 11/20/02]
- 11/18/2002 192 Letter to Clerk from W. Marsden, Jr. enclosing the original signature page for Declaration of Mark J. Hebert in support of Smith & Nephew's Motion to Stay (DI 189); requests replace the faxed version previously submitted with the enclosed original (ft) [Entry date 11/19/02]
- 11/18/2002 193 CERTIFICATION OF PERRY CLARK by ArthroCare Corp. re illegible documents; to the extent better copies could be located, they were produced to Smith & Nephew at Mr. Eggers' deposition on 11/13/02 (ft) [Entry date 11/19/02]
- 11/21/2002 194 SEALED Answer Brief Filed by ArthroCare Corp. [187-1] motion to Stay these proceedings pending the reexamination of U.S. Patent '538 - Reply Brief due 11/29/02 (ft) [Entry date 11/22/02]
- 11/21/2002 195 SEALED Appendix to Brief Filed by ArthroCare Corp. Appending [194-1] answer brief (ft) [Entry date 11/22/02]
- 11/22/2002 196 Letter to Judge Robinson from W. Marsden re addressing some issues have yet to resolve with ArthroCare regarding its document production; requests that the Court order ArthroCare to produce the requested documents and information (ft) [Entry date 11/25/02]
- 11/22/2002 197 Letter to Judge Robinson from M. Hebert re partially-illegible documents that came up during the Telecnf. on 11/7/02 (ft) [Entry date 11/25/02]
- 11/22/2002 198 MOTION by Smith & Nephew Inc. with Proposed Order to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum Answer Brief due 12/6/02 re: [198-1] motion (ft) [Entry date 11/25/02]
- 11/22/2002 199 SEALED Opening Brief Filed by Smith & Nephew Inc. [198-1] motion to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum (ft) [Entry date 11/25/02]
- 11/22/2002 200 SEALED Declaration of Thomas M. Johnston in support of DI # 198 (ft) [Entry date 11/25/02]
- 11/25/2002 201 Letter to Judge Robinson from K. Jacobs Loudon enclosing DI # 202, a proposed Revised Scheduling Order (ft)
- 11/25/2002 202 Proposed Revised Scheduling Order filed by ArthroCare Corp. (ft)
- 11/25/2002 203 TRANSCRIPT filed [0-0] discovery hearing for dates of 10/30/02; Judge Robinson presiding; Crt Rptr V. Gunning (ft)

- 11/25/2002 204 SEALED MOTION by Smith & Nephew Inc. to Strike Documents as Inadmissible hearsay Answer Brief due 12/9/02 re: [204-1] motion (ft)
- 11/25/2002 = Status conference held; Judge Robinson presiding; Crt Rptr Hawkins; decisions: (1) produce illegible documents-Denied; (2) Motion for Re-Argument on inequitable conduct-Denied; and (3) Trial will be bifurcated into liability and Damages (ft) [Entry date 12/02/02]
- 11/26/2002 205 Letter MOTION by ArthroCare Corp. to object to the disclosure of ArthroCare's confidential information to Kenneth Burchfiel, Smith & Nephew's proposed patent law expert Arthrocare objected to the disclosure; Mr. Burchfiel has no need to view ArthroCare's confidential information; should not be permitted access to ArthroCare's confidential information re: [205-1] motion (ft)
- 11/27/2002 206 Memorandum ORDER denying [187-1] motion to Stay these proceedings pending the reexamination of U.S. Patent '536; see order for reasons; denying [172-1] motion to Strike [167-1] answer brief(Arthrocare Corporation's Opposition to Smith & Nephew's Motion for Reargument), denying [160-1] motion for Reconsideration of a portion of the Court's [141-1] order, granting [111-1] motion for Leave to File amended answer and counterclm; However, discovery and trial of dft's newly added counterclaim for antitrust violations are stayed consistent with the ruling on the issues of damages and willfulness; granting [107-1] motion to Bifurcate Willfulness and Damages, granting [107-2] motion to Stay Discovery; discovery on the issues of willfulness and damages will be stayed until after the verdict on infringement and invalidity has been returned; these issues will be tried to a new jury; Dft's claim of privilege pertaining to redactions in certain documents (DI # 180) is denied; court finds that the info. redacted is equivalent to the info. required to be included in a privilege log, and thus not privileged info.(signed by Judge Sue L. Robinson) copies to: cnsl (ft)
- 11/27/2002 207 Letter to Clerk from K. Walter, Jr. re hearing before Judge Robinson yesterday; counsel for Smith & Nephew distributed the attached Table entitled Comparison of '592 and '536 Patent Claim Language; submitting for filing with the court; also filing separately, the Supplemental Declaration of Mark Hebert (DI # 208), which was also distributed at the hearing (ft)
- 11/27/2002 208 Supplemental Declaration of Mark J. Hebert in support of Smith & Nephew's Motion to Stay (ft)
- 11/27/2002 209 TRANSCRIPT filed for Oral Argument for dates of 11/25/02; Judge Robinson presiding; Crt Rptr. Hawkins Reporting Service (ft) [Entry date 12/02/02]
- 11/27/2002 219 Amended ANSWER to complaint and COUNTERCLAIM by Smith & Nephew Inc. ; jury demand against ArthroCare Corp. (rd) [Entry date 12/23/02]
- 11/27/2002 = So Ordered mootng [204-1] motion to Strike Documents as Inadmissible hearsay per D.J. # 206 (Memorandum Order) (ft) [Entry date 04/09/03]
- 12/02/2002 210 Letter to Judge Robinson from J. Blumenfeld re proposed revised scheduling order filed on 11/25/02 (DI # 201 and 202); now that the stay motion has been denied, would like to get a schedule in place promptly; request that it be entered (ft) [Entry date 12/03/02]
- 12/03/2002 211 Letter to Judge Robinson from J. Blumenfeld re 11/27/02 Order; granted Smith & Nephew's motion to amend its answer to assert an antitrust counterclaim; stayed discovery and trial on that counterclaim until after the trial of the patent issues; it is ArthroCare's understanding that it need not respond to the antitrust counterclaim until after the patent trial (ft) [Entry date 12/04/02]
- 12/03/2002 212 Letter to Judge Robinson from W. Marsden, Jr. responding to DI # 210 requesting entry of ArthroCare's proposed scheduling order; Smith & Nephew opposes entry of the proposed scheduling order; enclosing Smith & Nephew's proposed scheduling order; request entry; alternatively, request a teleconference to resolve scheduling issues (ft) [Entry date 12/04/02]
- 12/03/2002 214 SEALED Letter to The Honorable Sue L. Robinson from Jack R. Blumenfeld (ft) [Entry date 12/06/02]

- 12/04/2002 213 Letter to Judge Robinson from J. Blumenfeld re Smith & Nephew's letter of 12/3/02 and proposed scheduling order; parties have proposed different paths; available for a telephone conference (ft) [Entry date 12/06/02]
- 12/09/2002 215 STIPULATION to extend time for Ethicon, Inc. to file an answering brief in opposition to DI # 198; with proposed order (ft) [Entry date 12/10/02]
- 12/10/2002 216 SEALED Letter to Chief Judge Sue L. Robinson from William J. Marsden, Jr. responding to outstanding document production issues with Exhibits A through H (ft) [Entry date 12/11/02]
- 12/11/2002 = So Ordered granting [215-1] stipulation reset Answer Brief Deadline to 1/17/03 re: [198-1] motion to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 12/11/2002 217 Letter to Judge Robinson from W. Marsden, Jr. responding to Ms. Jacobs Loudon's letter of 11/26/02 (DI # 204); request that the Court overrule ArthroCare's objection and allow Smith & Nephew to show confidential material to its patent law expert (ft) [Entry date 12/12/02]
- 12/23/2002 218 Letter to Judge Robinson from J. Blumenfeld requesting a conference with the Court so that a schedule for the remainder of the case can be put into place leading to the 4/28/03 trial date (ft)
- 12/26/2002 220 Letter to Judge Robinson from W. Marsden, Jr. re DI # 218; letter of 12/23/02 requesting a teleconf. to set a schedule for the remainder of this case; Smith & Nephew would have no objection to the Court extending the trial date to allow time for decision on the Markman issues and summary judgment; seek Court's assistance in narrowing the issues for trial; request that the Court schedule a date two weeks before burden expert reports are due that ArthroCare must narrow the claims to the handful they wish to take to trial (ft) [Entry date 12/30/02]
- 01/02/2003 221 Letter to Judge Robinson from J. Blumenfeld responding to Smith & Nephew's 12/26 letter concerning the setting of a schedule and the 4/28/03 trial date (DI # 220); no reason why this case cannot be ready for trial 4 months from now; ArthroCare again requests a conference to get the scheduling impasse resolved (ft) [Entry date 01/03/03]
- 01/09/2003 = Deadline updated; set Status Conference for 2:00 1/22/03 per recent filings by the parties re scheduling matters (rd)
- 01/09/2003 222 Letter to Judge Robinson from K. Jacobs Loudon confirming that the Court has set an in-person status conference on 1/22/03 at 2:00 p.m. (ft) [Entry date 01/10/03]
- 01/17/2003 223 SEALED Answer Brief Filed by Ethicon, Inc [198-1] motion to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum - Reply Brief due 1/24/03 (rd) [Entry date 01/21/03]
- 01/22/2003 224 Steno Notes for 1/22/03 Status Conference; Judge Robinson presiding; Crt Rptr. L. Dibbs (ft) [Entry date 01/23/03]
- 01/22/2003 = Status conference held; Judge Robinson presiding; crt. rptr. L. Dibbs (rd) [Entry date 01/23/03]
- 01/22/2003 = So Ordered mootng [198-1] motion to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum; per Status Conference 1/22/03 (ft) [Entry date 04/09/03]
- 01/23/2003 225 Revised SCHEDULING ORDER; on or before 1/29/03 deft. shall submit to pltf. its final claim construction; on or before 2/5/03 pltf. shall file its expert report(s) on issues for which it has the burden of proof (most notably infringement); deft. shall file its rebuttal expert report by 2/19/03; by 2/12/03 deft. shall file its expert report(s) for which it has the burden of proof (most notably invalidity); pltf. shall file rebuttal expert report by 2/26/03; summary judgment motions due 3/4/03; oral argument shall be 4/1/03 at 4:30; all motions in limine due 4/1/03 with responses due 4/8/03; setting Pretrial conference for 4:30 4/15/03 ; Jury

- Trial Date Deadline 9:30 4/28/03 ; See order for further details (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 01/23/2003 = Deadline updated; Oral Arugment on Summary Jgm. Motions for 4:30 4/1/03 per DI#225 (rd)
- 01/24/2003 226 TRANSCRIPT filed [0-0] status conference for dates of 1/22/03; Judge Robinson presiding; Crt Rptr. L. Dibbs (ft)
- 01/27/2003 227 SEALED Reply Brief Filed by Smith & Nephew Inc. [198-1] motion to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum (ft) [Entry date 01/29/03]
- 01/27/2003 228 Declaration of Mark J. Hebert in support of DI # 227 (ft) [Entry date 01/29/03]
- 01/27/2003 229 Notice of Deficiency from the court to defendant Smith & Nephew Inc.; no original signature on DI # 228 (ft) [Entry date 01/29/03]
- 01/28/2003 230 Letter to Clerk from K. Walter, Jr. enclosing original signature page for DI # 228 which was filed on 1/27/03; please replace the faxed version previously submitted with the enclosed original (ft) [Entry date 01/29/03]
- 01/29/2003 231 Letter MOTION by ArthroCare Corp. to object to the disclosure of ArthroCare's confidential information to Ronald Panitch, Smith & Nephew's proposed patent law expert re: [231-1] motion (ft) [Entry date 01/30/03]
- 01/30/2003 232 Letter to Clerk from K. Walter, Jr. enclosing replacement Exhibits I and O which contain the correct letters to Declaration of Mark J. Hevert in Support of Smith & Nephew's Reply Brief in Support of its Motion to Compel Ethicon, which was filed on 1/27/03; replace the attached exhibits with version previously submitted with the original (ft) [Entry date 01/31/03]
- 01/31/2003 233 Letter to Judge Robinson from S. Balick requesting oral argument on deft.'s motion to compel (D.I. 198). (rd) [Entry date 02/03/03]
- 02/03/2003 234 STIPULATION to extend time for Ethicon to respond to the counterclaim; with proposed order (rd) [Entry date 02/04/03]
- 02/05/2003 = So Ordered granting [234-1] stipulation; Ethicon must respond to deft.'s counterclaim within 30 days after Ethicon's cnsl. receives rlc. from deft. Smith & Nephew's cnsl. that there has been a verdict in the patent trial (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 02/10/2003 235 Letter to Judge Robinson from W. Marsden, Jr. requesting immediate telecnf. with court to address pltf.'s failure to limit the asserted claims (rd)
- 02/11/2003 236 Letter to Judge Robinson from J. Blumenfeld responding to deft.'s letter of 2/10/03 (rd)
- 02/11/2003 = Deadline updated; set Telephone Conference for 7:30 2/13/03 per req. made in D.I. #235 (rd) [Edit date 02/11/03]
- 02/11/2003 237 Letter to Judge Robinson from K. Walter, Jr. re 2/13/03 telecnf. and req. for relief from the 2/12/03 due date for deft.'s invalidity expert reports; req. court hold the due date for deft. until after the telecnf. date; cnsl. for pltf. opposes this request. (rd)
- 02/12/2003 238 Letter to Judge Robinson from K. Walter responding to J. Blumenfeld's letter D.I. 231. (rd)
- 02/13/2003 = Tele-conference held; Judge Robinson presiding; crt. rptr. K. Maurer present. (rd) [Entry date 02/14/03]
- 02/13/2003 = So Ordered mootng [205-1] letter/motion to object to the disclosure of ArthroCare's confidential information to Kenneth Burchfiel, Smith & Nephew's proposed patent law expert; per Telephone Conference of 2/13/03 (ft) [Entry date 04/09/03] [Edit date 04/09/03]
- 02/13/2003 = So Ordered mootng [231-1] motion to object to the disclosure of ArthroCare's confidential information to Ronald Panitch, Smith & Nephew's proposed patent law expert; per Telephone Conference of 2/13/03 (ft) [Entry date 04/09/03]

- 02/14/2003 239 TRANSCRIPT filed [0-0] telephone conference for dates of 2/13/03; Judge Robinson presiding; crt. rpt. K. Maurer (rd)
- 02/14/2003 240 Steno Notes for 2/13/03 telecmt.; Judge Robinson presiding; crt. rpt. K. Maurer. (rd) [Entry date 02/19/03]
- 02/20/2003 241 STIPULATION to extend time for deft. to serve rebuttal expert reports with proposed order (rd)
- 02/21/2003 = So Ordered granting [241-1] stipulation extending time for deft. to serve its rebuttal expert reports until 2/21/03 (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 02/24/2003 242 CERTIFICATE OF SERVICE by ArthroCare Corp. re Opening Expert Report of Dr. S. Nahum Goldberg (R) [Entry date 02/27/03]
- 03/04/2003 243 CERTIFICATE OF SERVICE by ArthroCare Corp. re Expert Reports of (1) Creighton Hoffman, (2) Charles Van Horn, (3) Dr. S. Nahum Goldberg and Dr. Elliott H. Leitman. (rd) [Entry date 03/05/03]
- 03/04/2003 244 ArthroCare Corp. Opening Claim Construction Brief (rd) [Entry date 03/05/03]
- 03/04/2003 245 SEALED Appendix to Brief Filed by ArthroCare Corp. Appending D.I. 244 re claim construction (rd) [Entry date 03/05/03]
- 03/04/2003 246 SEALED Smith & Nephew Inc. Opening Claim Construction Brief (rd) [Entry date 03/05/03]
- 03/04/2003 247 MOTION by ArthroCare Corp. for partial Summary Judgment that the asserted claims of the patents-in-suit are not invalid due to obviousness or based on an alleged on-sale bar or public use Answer Brief due 3/18/03 re: [247-1] motion (rd) [Entry date 03/05/03]
- 03/04/2003 248 Opening Brief Filed by ArthroCare Corp. [247-1] motion for partial Summary Judgment that the asserted claims of the patents-in-suit are not invalid due to obviousness or based on an alleged on-sale bar or public use (rd) [Entry date 03/05/03]
- 03/04/2003 249 MOTION by ArthroCare Corp. for partial Summary Judgment that deft. infringes the asserted claims of the '882 patent Answer Brief due 3/18/03 re: [249-1] motion (rd) [Entry date 03/05/03]
- 03/04/2003 250 SEALED Opening Brief Filed by ArthroCare Corp. [249-1] motion for partial Summary Judgment that deft. infringes the asserted claims of the '882 patent (rd) [Entry date 03/05/03]
- 03/04/2003 251 MOTION by ArthroCare Corp. with Proposed Order for Partial Summary Judgment that deft. infringes claim 1 of the '592 patent Answer Brief due 3/18/03 re: [251-1] motion (rd) [Entry date 03/05/03]
- 03/04/2003 252 SEALED Opening Brief Filed by ArthroCare Corp. [251-1] motion for Partial Summary Judgment that deft. infringes claim 1 of the '592 patent (rd) [Entry date 03/05/03]
- 03/04/2003 253 SEALED Appendix to Brief Filed by ArthroCare Corp. Appending [252-1] opening brief, [250-1] opening brief, [248-1] opening brief (rd) [Entry date 03/05/03]
- 03/04/2003 254 Letter to Judge Robinson from W. Marsden detailing a brief description of the filings made today with the court on behalf of deft. (rd) [Entry date 03/05/03]
- 03/04/2003 255 MOTION by Smith & Nephew Inc. with Proposed Order for partial Summary Judgment of non-infringement of U.S. Patents '536, '882, and '592 Answer Brief due 3/18/03 re: [255-1] motion (rd) [Entry date 03/05/03]
- 03/04/2003 256 SEALED Opening Brief Filed by Smith & Nephew Inc. [255-1] motion for partial Summary Judgment of non-infringement of U.S. Patents '536, '882, and '592 (rd) [Entry date 03/05/03]
- 03/04/2003 257 MOTION by Smith & Nephew Inc. with Proposed Order for Partial Summary Judgment of (1) nonenablement, (2) indefiniteness, and (3) lack of written

- description Answer Brief due 3/18/03 re: [257-1] motion (rd) [Entry date 03/05/03]
- 03/04/2003 258 SEALED Opening Brief Filed by Smith & Nephew Inc. [257-1] motion for Partial Summary Judgment of (1) nonenablement, (2) indefiniteness, and (3) lack of written description (rd) [Entry date 03/05/03]
- 03/04/2003 259 MOTION by Smith & Nephew Inc. with Proposed Order for Summary Judgment to enforce the settlement agreement removing control RF product from the case Answer Brief due 3/18/03 re: [259-1] motion (rd) [Entry date 03/05/03] [Edit date 03/05/03]
- 03/04/2003 260 SEALED Opening Brief Filed by Smith & Nephew Inc. [258-1] motion for Summary Judgment to enforce the settlement agreement removing control RF product from the case (rd) [Entry date 03/05/03] [Edit date 03/05/03]
- 03/04/2003 261 MOTION by Smith & Nephew Inc. with Proposed Order for Summary Judgment of invalidity based on prior art Answer Brief due 3/18/03 re: [261-1] motion (rd) [Entry date 03/05/03]
- 03/04/2003 262 SEALED Opening Brief Filed by Smith & Nephew Inc. [261-1] motion for Summary Judgment of invalidity based on prior art (rd) [Entry date 03/05/03]
- 03/04/2003 263 SEALED Declaration of William J. Marsden, Jr. in support of deft.'s summary jgm. motions filed 3/4/03 (rd) [Entry date 03/05/03]
- 03/04/2003 264 SEALED Declaration of William J. Marsden, Jr. Volume 1 in support of Def.'s summary jgm. motions filed 3/4/03 (rd) [Entry date 03/05/03]
- 03/04/2003 265 SEALED Declaration of William J. Marsden, Jr. Volume 2 in support of Def.'s summary jgm. motions filed 3/4/03 (rd) [Entry date 03/05/03]
- 03/04/2003 266 SEALED Declaration of William J. Marsden, Jr. Volume 3 in support of Def.'s summary jgm. motions filed 3/4/03 (rd) [Entry date 03/05/03]
- 03/04/2003 267 SEALED Declaration of William J. Marsden, Jr. Volume 4 in support of Def.'s summary jgm. motions filed 3/4/03 (rd) [Entry date 03/05/03]
- 03/04/2003 268 SEALED Declaration of William J. Marsden, Jr. Volume 5 in support of Def.'s summary jgm. motions filed 3/4/03 (rd) [Entry date 03/05/03]
- 03/04/2003 269 Letter to Clerk from E. Joswick enclosing two sets of the Table of Authorities for deft.'s opening claim construction brief (rd) [Entry date 03/05/03]
- 03/05/2003 270 SEALED Joint Claim Construction Statement (rd)
- 03/17/2003 271 Letter to Judge Robinson from J. Blumenfeld advising that on 3/14/03, the Patent Office issued a Notice of Intent to Issue a Reexamination Certificate, a copy of which is attached as Exhibit A (ft) [Entry date 03/18/03]
- 03/17/2003 272 MOTION by Smith & Nephew Inc. with Proposed Order to Strike the Expert Reports of Creighton G. Hoffman and Elliott H. Leitman Answer Brief due 3/31/03 re: [272-1] motion (ft) [Entry date 03/18/03]
- 03/17/2003 273 SEALED Opening Brief Filed by Smith & Nephew Inc. [272-1] motion to Strike the Expert Reports of Creighton G. Hoffman and Elliott H. Leitman (ft) [Entry date 03/18/03]
- 03/18/2003 274 MOTION by ArthroCare Corp. to Strike the Roos Declaration Answer Brief due 4/1/03 re: [274-1] motion (ft) [Entry date 03/19/03]
- 03/18/2003 275 SEALED Answer Brief Filed by ArthroCare Corp. [259-1] motion for Summary Judgment to enforce the settlement agreement removing control RF product from the case - Reply Brief due 3/25/03 (ft) [Entry date 03/19/03]
- 03/18/2003 276 Declaration of John T. Raffle (ft) [Entry date 03/19/03]
- 03/18/2003 277 SEALED Declaration of Philip E. Eggers in Opposition to Smith & Nephew's Motion for Sum. Jgm. of Invalidity based on Prior Art (ft) [Entry date 03/19/03] [Edit date 03/19/03]
- 03/18/2003 278 SEALED Declaration of Creighton G. Hoffman (ft) [Entry date 03/19/03]

- 03/18/2003 279 SEALED Answer Brief Filed by ArthroCare Corp. [255-1] motion for partial Summary Judgment of non-infringement of U.S. Patents '536, '882, and '592 - Reply Brief due 3/25/03 (ft) [Entry date 03/19/03]
- 03/18/2003 280 SEALED Answer Brief Filed by ArthroCare Corp. [261-1] motion for Summary Judgment of invalidity based on prior art - Reply Brief due 3/25/03 (ft) [Entry date 03/19/03]
- 03/18/2003 281 SEALED Answering Brief by ArthroCare Corp. in opposition to [246-1] Opening Claim Construction Brief (ft) [Entry date 03/19/03]
- 03/18/2003 282 SEALED Responsive Claim Construction Brief by Smith & Nephew Inc. (ft) [Entry date 03/19/03]
- 03/18/2003 283 SEALED Answer Brief Filed by Smith & Nephew Inc. [247-1] motion for partial Summary Judgment that the asserted claims of the patents-in-suit are not invalid due to obviousness or based on an alleged on-sale bar or public use - Reply Brief due 3/25/03 (ft) [Entry date 03/19/03]
- 03/18/2003 284 Answer Brief Filed by Smith & Nephew Inc. [249-1] motion for partial Summary Judgment that defl. infringes the asserted claims of the '882 patent - Reply Brief due 3/25/03 (ft) [Entry date 03/19/03]
- 03/18/2003 285 SEALED Answer Brief Filed by Smith & Nephew Inc. [251-1] motion for Partial Summary Judgment that defl. infringes claim 1 of the '592 patent - Reply Brief due 3/25/03 (ft) [Entry date 03/19/03]
- 03/18/2003 286 SEALED Declaration of Eugene B. Joswick (ft) [Entry date 03/19/03]
- 03/18/2003 287 SEALED Declaration of Dr. S. Nahum Goldberg (Vol. 1) (ft) [Entry date 03/19/03]
- 03/18/2003 288 SEALED Declaration of Dr. S. Nahum Goldberg (Vol. 2) (ft) [Entry date 03/19/03]
- 03/18/2003 289 SEALED Declaration of Dr. S. Nahum Goldberg (Vol. 3) (ft) [Entry date 03/19/03]
- 03/18/2003 290 SEALED Declaration of Dr. S. Nahum Goldberg (Vol. 4) (ft) [Entry date 03/19/03]
- 03/18/2003 291 SEALED Declaration of Dr. S. Nahum Goldberg (Vol. 5) (ft) [Entry date 03/19/03]
- 03/18/2003 292 SEALED Answer Brief Filed by ArthroCare Corp. [257-1] motion for Partial Summary Judgment of (1) nonenablement, (2) indefiniteness, and (3) lack of written description - Reply Brief due 3/25/03 (ft) [Entry date 03/19/03]
- 03/18/2003 293 Arthrocare's Covenant not to sue Smith & Nephew on certain claims of the patents in suit (ft) [Entry date 03/19/03]
- 03/20/2003 294 Letter to Clerk from K. Walter enclosing a Rule 7.1.1 Certificate for D.I. # 272; neglected to contact opposing cnsl. re the motion before filing, have since contacted and believe the motion will be opposed (ft)
- 03/21/2003 295 Letter to Judge Robinson from W. Marsden, Jr. responding to D.I. # 271; Smith & Nephew requests that it be given leave to take Examiner Mendez' deposition, presuming that the appropriate approval can be obtained from the Patent Office (ft) [Entry date 03/24/03] [Edit date 03/24/03]
- 03/25/2003 296 Reply Brief Filed by ArthroCare Corp. [249-1] motion for partial Summary Judgment that defl. infringes the asserted claims of the '882 patent (ft) [Entry date 03/26/03]
- 03/25/2003 297 Reply Brief Filed by ArthroCare Corp. [251-1] motion for Partial Summary Judgment that defl. infringes claim 1 of the '592 patent (ft) [Entry date 03/26/03]
- 03/25/2003 298 Reply Brief Filed by ArthroCare Corp. [247-1] motion for partial Summary Judgment that the asserted claims of the patents-in-suit are not invalid due to obviousness or based on an alleged on-sale bar or public use (ft) [Entry date 03/26/03]

- 03/25/2003 299 SEALED Reply Brief Filed by Smith & Nephew Inc. [259-1] motion for Summary Judgment to enforce the settlement agreement removing control RF product from the case (ft) [Entry date 03/26/03]
- 03/25/2003 300 SEALED Reply Brief Filed by Smith & Nephew Inc. [257-1] motion for Partial Summary Judgment of (1) nonenablement, (2) indefiniteness, and (3) lack of written description (ft) [Entry date 03/26/03]
- 03/25/2003 301 SEALED Reply Brief Filed by Smith & Nephew Inc. [255-1] motion for partial Summary Judgment of non-infringement of U.S. Patents '536, '882, and '592 (ft) [Entry date 03/26/03]
- 03/25/2003 302 SEALED Reply Brief Filed by Smith & Nephew Inc. [261-1] motion for Summary Judgment of invalidity based on prior art (ft) [Entry date 03/26/03]
- 03/25/2003 303 SEALED Declaration of Michael A. Choti (ft) [Entry date 03/26/03]
- 03/25/2003 304 SEALED Declaration of Kim H. Manwaring (ft) [Entry date 03/26/03]
- 03/25/2003 305 SEALED Declaration of Keith A. Walter, Jr. (ft) [Entry date 03/26/03]
- 03/25/2003 306 Declaration of Kenneth L. Taylor (ft) [Entry date 03/26/03]
- 03/25/2003 307 Notice of Deficiency from the court to defendant Smith & Nephew Inc.; no original signature on Declaration of Kenneth L. Taylor (D.I. # 306) (ft) [Entry date 03/26/03]
- 03/26/2003 = Deadline updated; Motion Hearing set for 2:00 4/1/03 (moved from 4:30 p.m.) for [274-1] motion to Strike the Roos Declaration, [272-1] motion to Strike the Expert Reports of Creighton G. Hoffman and Elliott H. Leitman, [261-1] motion for Summary Judgment of invalidity based on prior art, [259-1] motion for Summary Judgment to enforce the settlement agreement removing control RF product from the case, [257-1] motion for Partial Summary Judgment of (1) nonenablement, (2) indefiniteness, and (3) lack of written description, [255-1] motion for partial Summary Judgment of non-infringement of U.S. Patents '536, '882, and '592, [251-1] motion for Partial Summary Judgment that deft. infringes claim 1 of the '592 patent, [249-1] motion for partial Summary Judgment that deft. infringes the asserted claims of the '882 patent, [247-1] motion for partial Summary Judgment that the asserted claims of the patents-in-suit are not invalid due to obviousness or based on an alleged on-sale bar or public use, [231-1] motion to object to the disclosure of ArthroCare's confidential information to Ronald Panitch, Smith & Nephew's proposed patent law expert, [205-1] motion to object to the disclosure of ArthroCare's confidential information to Kenneth Burchfiel, Smith & Nephew's proposed patent law expert, [204-1] motion to Strike Documents as inadmissible hearsay, [198-1] motion to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum (rd)
- 03/26/2003 308 Declaration of Brian W. Napper (ft) [Entry date 03/27/03]
- 03/26/2003 309 Notice of Deficiency from the court to defendant Smith & Nephew Inc.; no original signature on Declaration of Brian W. Napper (D.I. # 308) (ft) [Entry date 03/27/03]
- 03/26/2003 310 CERTIFICATE OF SERVICE by Smith & Nephew Inc. re supplemental response to modified 1st set of interogs (No. 6) (ft) [Entry date 03/27/03]
- 03/26/2003 311 Letter to Clerk from K. Walter, Jr. enclosing the original signature page for the Declaration of Kenneth D. Taylor (D.I. # 306); replace the faxed version with the original (ft) [Entry date 03/27/03]
- 03/31/2003 312 Answer Brief Filed by ArthroCare Corp. [272-1] motion to Strike the Expert Reports of Creighton G. Hoffman and Elliott H. Leitman - Reply Brief due 4/7/03 (ft) [Entry date 04/01/03]
- 03/31/2003 313 CERTIFICATE OF SERVICE by ArthroCare Corp. re supplemental rebuttal expert report of Charles E. Van Horn (ft) [Entry date 04/01/03]
- 03/31/2003 314 MOTION by ArthroCare Corp. with Proposed Order for Timothy E. DeMasl to Appear Pro Hac Vice (ft) [Entry date 04/01/03]

- 03/31/2003 315 MOTION by Smith & Nephew Inc. with Proposed Order for Karen I. Boyd, Esquire to Appear Pro Hac Vice (ft) [Entry date 04/01/03]
- 04/01/2003 316 MOTION by ArthroCare Corp. in Limine to exclude the testimony of Smith & Nephew's Patent Law Expert, Ronald L. Panitch Answer Brief due 4/8/03 re: [316-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 317 MOTION by ArthroCare Corp. in Limine to preclude Smith & Nephew from relying on any undisclosed facts or defenses Answer Brief due 4/8/03 re: [317-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 318 UNOPPOSED MOTION by ArthroCare Corp. in Limine to preclude Smith & Nephew from referring to injunctive relief that may be sought as a result of a finding of infringement re: [318-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 319 MOTION by ArthroCare Corp. in Limine to preclude Smith & Nephew from referring to a purported control RF Settlement Agreement Answer Brief due 4/8/03 re: [319-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 320 MOTION by ArthroCare Corp. in Limine to preclude Smith & Nephew from referring to Arthrocare's withdrawal of certain claims Answer Brief due 4/8/03 re: [320-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 321 MOTION by ArthroCare Corp. in Limine to preclude Smith & Nephew from referring to Judge Orrick's December 1, 1998 interlocutory decision in the Ethicon case Answer Brief due 4/8/03 re: [321-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 322 MOTION by ArthroCare Corp. in Limine to try inequitable conduct to the Court and to preclude Smith & Nephew from raising issues of inequitable conduct before the jury Answer Brief due 4/8/03 re: [322-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 323 MOTION by ArthroCare Corp. in Limine that Smith & Nephew's indefiniteness defenses not be presented to the jury Answer Brief due 4/8/03 re: [323-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 324 SEALED MOTION by ArthroCare Corp. in Limine to preclude Smith & Nephew from referring to its antitrust counterclaim or allegedly harmful effects of Arthrocare's RF Devices Answer Brief due 4/8/03 re: [324-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 325 SEALED MOTION by Smith & Nephew Inc. in Limine 1 of 6 to exclude certain Arthrocare expert testimony Answer Brief due 4/8/03 re: [325-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 326 SEALED MOTION by Smith & Nephew Inc. in Limine 2 of 6 to exclude certain evidence related to Arthrocare's products Answer Brief due 4/8/03 re: [326-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 327 SEALED MOTION by Smith & Nephew Inc. in Limine 3 of 6 to exclude evidence of the reexamination of the '536 patent-in-suit Answer Brief due 4/8/03 re: [327-1] motion (ft) [Entry date 04/02/03] [Edit date 04/02/03]
- 04/01/2003 328 SEALED MOTION by Smith & Nephew Inc. in Limine 4 of 6 to exclude certain evidence related to licensing Answer Brief due 4/8/03 re: [328-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 329 SEALED MOTION by Smith & Nephew Inc. in Limine 5 of 6 to exclude certain Smith & Nephew documents Answer Brief due 4/8/03 re: [329-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 330 SEALED MOTION by Smith & Nephew Inc. in Limine 6 of 6 to exclude evidence related to the control RF product Answer Brief due 4/8/03 re: [330-1] motion (ft) [Entry date 04/02/03]
- 04/01/2003 331 SEALED Answer Brief Filed by Smith & Nephew Inc. [274-1] motion to Strike the Roos Declaration - Reply Brief due 4/8/03 (ft) [Entry date 04/02/03]
- 04/01/2003 = Oral Argument held; Judge Robinson presiding; Court Rptr. Hawkins; re: sum. jgm. motions (ft) [Entry date 04/03/03]

- 04/02/2003 = So Ordered granting [314-1] motion for Timothy E. DeMasi to Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (ft)
- 04/02/2003 = So Ordered granting [315-1] motion for Karen I. Boyd, Esquire to Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (ft)
- 04/02/2003 332 Letter to Judge Robinson from W. Marsden, Jr. responding to Court's request for an explanation of the length parties' joint claim construction statement (D.I. # 270) (ft) [Entry date 04/03/03]
- 04/02/2003 333 Letter to Judge Robinson from J. Blumenfeld responding to question about the 65-page joint claim construction chart (D.I. #270) (ft) [Entry date 04/03/03]
- 04/02/2003 334 SEALED Letter to Deputy Clerk Tassone from K. Walter, Jr. dated 4/2/03 enclosing replacement pages to motion in limine 4 of 6 (ft) [Entry date 04/03/03]
- 04/03/2003 335 TRANSCRIPT filed; oral argument for dates of 4/1/03; Judge Robinson presiding; Hawkins Reporting Service (ft)
- 04/07/2003 336 SEALED Reply Brief Filed by Smith & Nephew Inc. [272-1] motion to Strike the Expert Reports of Creighton G. Hoffman and Elliott H. Leitman (rd) [Entry date 04/08/03]
- 04/08/2003 337 Answer Brief Filed by Smith & Nephew Inc. [320-1] motion in Limine to preclude Smith & Nephew from referring to Arthrocare's withdrawal of certain claims (ft) [Entry date 04/09/03]
- 04/08/2003 338 Answer Brief Filed by Smith & Nephew Inc. [317-1] motion in Limine to preclude Smith & Nephew from relying on any undisclosed facts or defenses (ft) [Entry date 04/09/03]
- 04/08/2003 339 Answer Brief Filed by Smith & Nephew Inc. [321-1] motion in Limine to preclude Smith & Nephew from referring to Judge Orrick's December 1, 1998 interlocutory decision in the Ethicon case (ft) [Entry date 04/09/03]
- 04/08/2003 340 Answer Brief Filed by Smith & Nephew Inc. [323-1] motion in Limine that Smith & Nephew's indefiniteness defenses not be presented to the jury (ft) [Entry date 04/09/03]
- 04/08/2003 341 SEALED Answer Brief Filed by Smith & Nephew Inc. [324-1] motion in Limine to preclude Smith & Nephew from referring to its antitrust counterclaim or allegedly harmful effects of Arthrocare's RF Devices (ft) [Entry date 04/09/03]
- 04/08/2003 342 Answer Brief Filed by ArthroCare Corp. [325-1] motion in Limine 1 of 6 to exclude certain Arthrocare expert testimony (ft) [Entry date 04/09/03]
- 04/08/2003 343 SEALED Answer Brief Filed by ArthroCare Corp. [326-1] motion in Limine 2 of 6 to exclude certain evidence related to Arthrocare's products (ft) [Entry date 04/09/03]
- 04/08/2003 344 Answer Brief Filed by ArthroCare Corp. [327-1] motion in Limine 3 of 6 to exclude evidence of the reexamination of the '536 patent-in-suit (ft) [Entry date 04/09/03]
- 04/08/2003 345 SEALED Answer Brief Filed by ArthroCare Corp. [328-1] motion in Limine 4 of 6 to exclude certain evidence related to licensing (ft) [Entry date 04/09/03]
- 04/08/2003 346 SEALED Answer Brief Filed by ArthroCare Corp. [329-1] motion in Limine 5 of 6 to exclude certain Smith & Nephew documents (ft) [Entry date 04/09/03]
- 04/08/2003 347 SEALED Answer Brief Filed by ArthroCare Corp. [330-1] motion in Limine 6 of 6 to exclude evidence related to the control RF product (ft) [Entry date 04/09/03]
- 04/08/2003 348 Reply Brief Filed by ArthroCare Corp. [274-1] motion to Strike the Roos Declaration (ft) [Entry date 04/09/03]
- 04/08/2003 349 Answer Brief Filed by Smith & Nephew Inc. [322-1] motion in Limine to try inequitable conduct to the Court and to preclude Smith & Nephew from raising issues of inequitable conduct before the jury (ft) [Entry date 04/09/03]

- 04/08/2003 350 Answer Brief Filed by Smith & Nephew Inc. [316-1] motion in Limine to exclude the testimony of Smith & Nephew's Patent Law Expert, Ronald L. Panitch (ft) [Entry date 04/09/03]
- 04/08/2003 351 Letter to Judge Robinson from W. Marsden, Jr. notifying the Court that Smith & Nephew is not opposing ArthroCare's Motion in limine to preclude Smith & Nephew from referring to purported Control RF Settlement Agreement; Smith & Nephew's Motion in limine 6 of 6 seeks to exclude all evidence relating to the Control RF product; Smith & Nephew is not opposing ArthroCare's Unopposed Motion in Limine to preclude Smith & Nephew from referring to Injunctive Relief that may be sought as a result of a finding of infringement (ft) [Entry date 04/09/03]
- 04/09/2003 352 MEMORANDUM OPINION (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 04/09/2003 353 MEMORANDUM ORDER construing the disputed claim language in U.S. Patents '536, '882, and '592 as listed in this order(signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 04/09/2003 354 ORDER denying [261-1] motion for Summary Judgment of invalidity based on prior art, denying [259-1] motion for Summary Judgment to enforce the settlement agreement removing control RF product from the case, denying [257-1] motion for Partial Summary Judgment of (1) nonenablement, (2) indefiniteness, and (3) lack of written description, denying [255-1] motion for partial Summary Judgment of non-infringement of U.S. Patents '536, '882, and '592, denying [251-1] motion for Partial Summary Judgment that deft. infringes claim 1 of the '592 patent, denying [249-1] motion for partial Summary Judgment that deft. infringes the asserted claims of the '882 patent, denying [247-1] motion for partial Summary Judgment that the asserted claims of the patents-in-suit are not invalid due to obviousness or based on an alleged on-sale bar or public use (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 04/09/2003 355 Letter to Judge Robinson from J. Blumenfeld re key contested issue in case; whether the Roos '198 patent discloses electrically conductive fluid (ft) [Entry date 04/10/03]
- 04/10/2003 356 ArthroCare's Supplemental Covenant not to sue Smith & Nephew on certain claims of the patents-in-suit (ft) [Entry date 04/11/03]
- 04/10/2003 357 Joint Proposed Preliminary Jury instructions by ArthroCare Corp., Smith & Nephew Inc. (ft) [Entry date 04/11/03]
- 04/10/2003 358 Proposed Voir dire questions by ArthroCare Corp. (ft) [Entry date 04/11/03]
- 04/10/2003 359 Proposed Verdict Sheet filed by ArthroCare Corp. (ft) [Entry date 04/11/03]
- 04/10/2003 360 Joint PRETRIAL ORDER (ft) [Entry date 04/11/03]
- 04/10/2003 364 Proposed Voir dire questions by Smith & Nephew Inc. (rd) [Entry date 04/14/03]
- 04/10/2003 365 Proposed Verdict Sheet filed by Smith & Nephew Inc. (rd) [Entry date 04/14/03]
- 04/10/2003 366 Proposed Jury instructions by ArthroCare Corp., Smith & Nephew Inc. (rd) [Entry date 04/14/03]
- 04/11/2003 361 Letter to Clerk from K. Walter, Jr. enclosing original signature page for Declaration of Brian W. Napper (D.I. 308) (rd) [Entry date 04/14/03]
- 04/11/2003 362 Letter to Judge Robinson from K. Walter, Jr. re Mr. Blumenfeld's letter relating to deft.'s opposition to pltf.'s motion in limine to exclude the testimony of R. Panitch (rd) [Entry date 04/14/03]
- 04/11/2003 363 Letter to Clerk from K. Walter, Jr. enclosing replacement page 4 to deft.'s opposition to motion in limine to exclude the testimony of R. Panitch. (rd) [Entry date 04/14/03]
- 04/14/2003 367 MEMORANDUM ORDER denying [330-1] motion in Limine 6 of 6 to exclude evidence related to the control RF product, granting in part, denying in part

[329-1] motion in Limine 5 of 6 to exclude certain Smith & Nephew documents, granting [328-1] motion in Limine 4 of 6 to exclude certain evidence related to licensing, denying [327-1] motion in Limine 3 of 6 to exclude evidence of the reexamination of the '536 patent-in-suit, denying [326-1] motion in Limine 2 of 6 to exclude certain evidence related to Arthrocare's products, granting to the extent it relates to to claim const. and the fact that experts are limited by their reports [325-1] motion in Limine 1 of 6 to exclude certain Arthrocare expert testimony, conditionally granting [324-1] motion in Limine to preclude Smith & Nephew from referring to its antitrust counterclaim or allegedly harmful effects of Arthrocare's RF Devices, denying [323-1] motion in Limine that Smith & Nephew's indefiniteness defenses not be presented to the jury, granting [322-1] motion in Limine to try inequitable conduct to the Court and to preclude Smith & Nephew from raising issues of inequitable conduct before the jury, granting [321-1] motion in Limine to preclude Smith & Nephew from referring to Judge Orrick's December 1, 1998 interlocutory decision in the Ethicon case, granting [320-1] motion in Limine to preclude Smith & Nephew from referring to Arthrocare's withdrawal of certain claims, granting [319-1] motion in Limine to preclude Smith & Nephew from referring to a purported control RF Settlement Agreement, granting [318-1] motion in Limine to preclude Smith & Nephew from referring to injunctive relief that may be sought as a result of a finding of infringement, granting [317-1] motion in Limine to preclude Smith & Nephew from relying on any undisclosed facts or defenses, granting [316-1] motion in Limine to exclude the testimony of Smith & Nephew's Patent Law Expert, Ronald L. Panitch, granting [274-1] motion to Strike the Roos Declaration, denying [272-1] motion to Strike the Expert Reports of Creighton G. Hoffman and Elliott H. Leftman denying [198-1] motion to Compel Ethicon, Inc. to comply with subpoena Duces Tecum and Ad Testificandum (signed by Judge Sue L. Robinson) copies to: cnsl. (rd) [Edit date 04/14/03]

- 04/14/2003 368 MEMORANDUM by ArthroCare Corp. Objections to Def.'s Trial Exhibits (rd)
- 04/14/2003 369 Letter to Clerk from K. Walter, Jr. enclosing D.I. 370 for filing. (rd)
- 04/14/2003 370 MEMORANDUM by Smith & Nephew Inc. Objecting to Pltf.'s Trial Exhibit List (rd)
- 04/15/2003 = Pre-trial conference held; Judge Robinson presiding; Court Rptr. V. Gunning (ft) [Entry date 04/16/03]
- 04/16/2003 371 TRANSCRIPT filed [0-0] pre-trial conference for dates of 4/15/03; Judge Robinson presiding; crt rptr. V. Gunning (rd) [Entry date 04/22/03]
- 04/23/2003 372 Letter to Judge Robinson from J. Blumenfeld enclosing lists of companies, attorneys and law firms, witnesses and subject areas for the voir dire (ft) [Entry date 04/24/03]
- 04/23/2003 373 Letter to Judge Robinson from W. Marsden, Jr. re clarification of 4/9/03 Memorandum Opinion and Order (ft) [Entry date 04/24/03]
- 04/25/2003 374 Letter to Judge Robinson from J. Blumenfeld re request for clarification by Smith & Nephew (ft)
- 04/28/2003 375 Letter to Judge Robinson from K. Walter, Jr. informing the Court of Smith & Nephew's continued efforts to simplify the trial and some disputes have arisen in connection with efforts; request a teleconference at earliest convenience (ft)
- 04/28/2003 376 Letter to Judge Robinson from K. Jacobs Loudon enclosing Order dismissing with prejudice Smith & Nephew's declaratory jgm. counterclaim for invalidity due to obviousness (ft)
- 04/28/2003 377 Letter to Judge Robinson from J. Blumenfeld re evidentiary issues (ft)
- 04/28/2003 378 Letter to Judge Robinson from K. Jacobs Loudon requesting a sentence be added to the end of paragraph 1 on page 2 of the preliminary jury instructions (ft)
- 04/28/2003 379 Letter to Judge Robinson from W. Marsden, Jr. requesting that the Court issue

- an order requiring ArthroCare to bring its in-house counsel and vice president John Raffle to testify at trial (ft)
- 04/28/2003 380 SEALED Letter to Court Dated 4/28/03 (ft)
- 04/29/2003 381 Letter to Judge Robinson from J. Blumenfeld responding to def't.'s letter of 4/28/03 req. court to order pltf.'s in house cnsl., John Raffle, to testify at trial. (rd)
- 04/29/2003 382 SEALED Letter to Judge Robinson from William Marsden, Jr. (rd)
- 04/29/2003 = Deadline updated; set Telephone Conference for 4:00 4/29/03 (rd)
- 04/29/2003 383 Letter to Judge Robinson from K. Walter, Jr. responding to pltf.'s letter of 4/28/03 adding a proposed instruction on reexamination to the preliminary jury instr. (rd)
- 04/29/2003 = Tele-conference held; Judge Robinson presiding; crt. rptr. B. Gaffigan present. (rd) [Entry date 05/01/03]
- 04/30/2003 384 Voir dire to the Jury Panel (ft)
- 04/30/2003 385 Preliminary Jury Instructions (ft)
- 04/30/2003 386 Letter to Judge Robinson from W. Marsden, Jr. re Smith & Nephew's request to preclude ArthroCare from referring to, or offering any evidence at trial related to nonobviousness, particularly any evidence or argument related to secondary considerations of nonobviousness (ft)
- 04/30/2003 = Jury trial held DAY 1; Judge Robinson presiding; Court Rptrs K. Maurer/B. Gaffigan; Jury Selection and Instruction (ft)
- 04/30/2003 387 Letter to Judge Robinson from W. Marsden, Jr. requesting reconsideration of ruling this morning that ArthroCare may introduce evidence of Smith & Nephew's alleged copying of the ArthroCare devices (ft) [Entry date 05/01/03]
- 04/30/2003 388 Steno Notes for 4/30/03 Jury Trial; Judge Robinson presiding; Court Rptr. B. Gaffigan (ft) [Entry date 05/01/03]
- 04/30/2003 389 Steno Notes for 4/29/03 teleconference; Judge Robinson presiding; Court Rptr. B. Gaffigan (ft) [Entry date 05/01/03]
- 04/30/2003 390 TRANSCRIPT filed [0-0] telephone conference for dates of 4/29/03; Judge Robinson presiding; crt. rptr. B. Gaffigan (rd) [Entry date 05/01/03]
- 05/01/2003 = Jury trial held DAY 2; Judge Robinson presiding; Court Rptr V. Gunning (ft)
- 05/02/2003 = Jury trial held DAY 3; Judge Robinson presiding; Court Rptrs. K. Maurer/B. Gaffigan (ft)
- 05/05/2003 391 SEALED Letter to Honorable Sue L. Robinson from Mark J. Hebert (ft) [Edit date 05/05/03]
- 05/05/2003 392 MOTION by ArthroCare Corp. to preclude Dr. Michael Choti from Testifying about the Prior Art Answer Brief due 5/19/03 re: [392-1] motion (ft)
- 05/05/2003 393 MOTION by ArthroCare Corp. to preclude Dr. Kim Marwaring from testifying about the Codman ME2 and a new report produced on May 4, 2003 Answer Brief due 5/19/03 re: [393-1] motion (ft)
- 05/05/2003 394 Steno Notes for 5/2/03; daily notes; Judge Robinson presiding; Jury Trial; crt. rptr. B. Gaffigan (rd)
- 05/05/2003 = Jury trial held DAY 4; Judge Robinson presiding; Court Rptr. V. Gunning; D.I. # 392 is denied and D.I. # 393 is granted in part and denied in part per trial ruling by Judge Robinson (ft)
- 05/05/2003 = So Ordered (Judge Robinson Ruled In Court During Trial) granting in part, denying in part [393-1] motion to preclude Dr. Kim Marwaring from testifying about the Codman ME2 and a new report produced on May 4, 2003, denying [392-1] motion to preclude Dr. Michael Choti from Testifying about the Prior Art (ft) [Entry date 05/06/03]
- 05/06/2003 = Jury trial held DAY 5; Judge Robinson presiding; Court Rptrs. K. Maurer/B.

Gaffigan (ft)

- 05/06/2003 395 Letter to Judge Robinson from J. Parrett, Jr. enclosing parties' proposed jury instructions in hard copy and on disk. (rd)
- 05/06/2003 396 Proposed Jury Instructions by ArthroCare Corp., Smith & Nephew Inc. (rd)
- 05/07/2003 397 Steno Notes for 5/6/03 Daily Notes of Jury Trial; B. Gaffigan (rd)
- 05/07/2003 = Jury trial held DAY 6; Judge Robinson presiding; Court Rptr. V. Gunning; Deft. moves under Rule 50; Judge Robinson reserves jgm. (ft)
- 05/08/2003 398 ORDER directing Clerk of the court to furnish lunch for 8 jurors on May 1 and 2, 2003 (signed by Judge Sue L. Robinson) copies to: financial admin. (rd)
- 05/08/2003 = Jury trial held DAY 7; Judge Robinson presiding; Court Rptrs. K. Maurer/ B. Gaffigan present (ft)
- 05/09/2003 399 Steno Notes for 5/8/03; Daily Jury Trial Note; crt. rptr. B. Gaffigan (rd)
- 05/09/2003 400 SEALED MOTION by Smith & Nephew Inc. Rule 50(A) for Judgment as a Matter of Law Answer Brief due 5/23/03 re: [400-1] motion (rd)
- 05/09/2003 401 ORDER directing Clerk of the court to furnish lunch for eight (8) jurors from 5/5-9/03(signed by Judge Sue L. Robinson) copies to: Financial Admin. (rd)
- 05/09/2003 402 MOTION by ArthroCare Corp. for Judgment as a Matter of Law Under F.R.C.P. 50(a) Answer Brief due 5/23/03 re: [402-1] motion (rd)
- 05/09/2003 403 ArthroCare Corp.'s Revised Supplemental Covenant not to sue Smith & Nephew on certain claims of the patents-in-suit (rd)
- 05/09/2003 = Jury trial held DAY 8; Judge Robinson presiding; Court Rptr. V. Gunning present; Deft renews Rule 50 motion; Pltf's Rule 50 Motion; Judge Robinson reserves jgm. (ft)
- 05/09/2003 406 Proffer of Evidence of Warren P. Heim (rd) [Entry date 05/13/03]
- 05/09/2003 407 Proffer of Evidence of Kim H. Marwaring (rd) [Entry date 05/13/03]
- 05/12/2003 404 Jury Charge (rd)
- 05/12/2003 405 JURY VERDICT for ArthroCare Corp.; finding of infringement by Smith & Nephew on the '536, '882, and '592 patents; finding of no invalidity of the '536, '882, '592 patents (ft)
- 05/12/2003 = Jury trial held DAY 9; Judge Robinson presiding; Court Rptrs. K. Maurer and B. Gaffigan present; Jury deliberation and verdict (ft)
- 05/12/2003 = Mooting [402-1] motion for Judgment as a Matter of Law Under F.R.C.P. 50(a), mootng [400-1] motion Rule 50(A) for Judgment as a Matter of Law per Jury Verdict (ft) [Entry date 06/11/03]
- 05/13/2003 408 Steno Notes for 5/12/03; Daily Notes; final day; jury verdict; crt. rptr. B. Gaffigan (rd)
- 05/13/2003 409 TRANSCRIPT filed [0-0] jury trial for dates of 4/30/03; Judge Robinson presiding; Daily Copy; volume A. (rd) [Edit date 05/13/03]
- 05/13/2003 410 TRANSCRIPT filed [0-0] jury trial for dates of 5/1/03; Judge Robinson presiding; Daily Copy; Volume B (rd) [Edit date 05/13/03]
- 05/13/2003 411 TRANSCRIPT filed [0-0] jury trial for dates of 5/2/03; Judge Robinson presiding; Daily copy; Volume C. (rd) [Edit date 05/13/03]
- 05/13/2003 412 TRANSCRIPT filed [0-0] jury trial for dates of 5/5/03; Judge Robinson presiding; Daily Copy; Volume D. (rd) [Edit date 05/13/03]
- 05/13/2003 413 SEALED TRANSCRIPT filed [0-0] jury trial for dates of 5/5/03; Judge Robinson presiding; Volume "DD" (rd)
- 05/13/2003 414 TRANSCRIPT filed [0-0] jury trial for dates of 5/6/03; Judge Robinson presiding; Daily copy; Volume E (rd)
- 05/13/2003 415 TRANSCRIPT filed [0-0] jury trial for dates of 5/7/03; Judge Robinson

- presiding; Daily Copy; Volume F (rd)
- 05/13/2003 416 TRANSCRIPT filed [0-0] jury trial for dates of 5/8/03; Judge Robinson presiding; Daily copy; Volume G (rd)
- 05/13/2003 417 TRANSCRIPT filed [0-0] jury trial for dates of 5/9/03; Judge Robinson presiding; Daily Copy; Volume H (rd)
- 05/13/2003 418 TRANSCRIPT filed [0-0] jury trial for dates of 5/12/03; Judge Robinson presiding; Daily copy; Volume I (rd)
- 05/14/2003 419 Letter to Judge Robinson from K. Walter re briefing schedule for inequitable conduct (rd) [Entry date 05/15/03]
- 05/16/2003 420 Letter to Judge Robinson from J. Blumenfeld responding to deflt.'s letter of 5/14/03 re post-trial briefing. (rd) [Entry date 05/20/03]
- 05/19/2003 421 Sleno Notes for 4/30/03 through 5/12/03; Daily Notes of Jury Trial; Judge Robinson presiding; crt. rpt. K. Maurer (rd) [Entry date 05/20/03]
- 05/19/2003 423 Letter to Judge Robinson from W. Marsden responding to Mr. Blumenfeld's letter of 5/16/03 re deflt.'s inequitable conduct defense. (rd) [Entry date 05/21/03]
- 05/20/2003 422 ORDER directing the USMS to furnish lunch for eight jurors and one CSO during their deliberations on 5/12/03 (signed by Judge Sue L. Robinson) copies to: Financial Admin. (rd)
- 05/20/2003 424 MOTION by ArthroCare Corp. for Permanent Injunction Answer Brief due 6/3/03 re: [424-1] motion (rd) [Entry date 05/21/03]
- 05/20/2003 425 SEALED Opening Brief Filed by ArthroCare Corp. [424-1] motion for Permanent Injunction (rd) [Entry date 05/21/03]
- 05/20/2003 426 Letter to Judge Robinson from J. Blumenfeld re inequitable conduct defense. (rd) [Entry date 05/21/03]
- 05/20/2003 427 MOTION by ArthroCare Corp. for Entry of Judgment of no Inequitable Conduct Answer Brief due 6/3/03 re: [427-1] motion (rd) [Entry date 05/21/03]
- 05/20/2003 428 Opening Brief Filed by ArthroCare Corp. [427-1] motion for Entry of Judgment of no Inequitable Conduct (rd) [Entry date 05/21/03]
- 05/27/2003 429 MOTION by ArthroCare Corp. to Dismiss Deflt.'s Antitrust Counterclaim Answer Brief due 6/10/03 re: [429-1] motion (rd) [Entry date 05/28/03]
- 05/27/2003 430 Opening Brief Filed by ArthroCare Corp. [429-1] motion to Dismiss Deflt.'s Antitrust Counterclaim (rd) [Entry date 05/28/03]
- 05/28/2003 = Deadline updated; set Telephone Conference for 3:30 6/9/03 per filing of D.I. 419 (rd)
- 05/29/2003 431 Letter to Deputy Clerk DiMeo from K. Walter confirming teleconf. for 6/9/03 at 3:30 p.m.; cnsl. for all parties including Ethicon will be present. (rd) [Entry date 05/30/03]
- 05/29/2003 432 SEALED MOTION by Smith & Nephew Inc. to Modify Protective Order Answer Brief due 6/12/03 re: [432-1] motion (ft) [Entry date 06/02/03]
- 05/30/2003 433 SEALED Declaration of Keith A. Walter, Jr. in support of D.I. # 432 (ft) [Entry date 06/02/03]
- 05/30/2003 434 Letter to Judge Robinson from J. Blumenfeld re scheduling matters which ArthroCare would like to put on the agenda for the telephone conf. on 6/9/03 at 3:30 p.m. (ft) [Entry date 06/03/03]
- 06/03/2003 435 SEALED Answer Brief Filed by ArthroCare Corp. [432-1] motion to Modify Protective Order - Reply Brief due 6/10/03 (ft) [Entry date 06/04/03]
- 06/04/2003 436 SEALED Answer Brief Filed by Smith & Nephew Inc. [424-1] motion for Permanent Injunction - Reply Brief due 6/11/03 (ft) [Entry date 06/05/03]
- 06/04/2003 437 COMBINED CROSS MOTION by Smith & Nephew Inc. to Strike [427-1]

- motion for Entry of Judgment of no Inequitable Conduct AND ANSWER BRIEF to Motion for entry of jgm of no inequitable conduct (ft) [Entry date 06/05/03]
- 06/04/2003 = 2nd Part of DI # 437; COMBINED Answer Brief Filed by Smith & Nephew Inc. [427-1] motion for Entry of Judgment of no Inequitable Conduct - Reply Brief due 6/11/03 and CROSS MOTION to strike ArthroCare's Motion for Entry of Jgm of No Inequitable Conduct (ft) [Entry date 06/05/03] [Edit date 06/05/03]
- 06/06/2003 438 Letter to Judge Robinson from K. Walter responding to Mr. Blumenfeld's 5/30/03 letter concerning the scheduling matters which ArthroCare would like to put on the agenda for the telephone conf. on 6/9/03 (D.I. # 430); would like to address its pending motion to modify the stipulated protective order (ft) [Entry date 06/09/03]
- 06/06/2003 439 SEALED Reply Brief Filed by Smith & Nephew Inc. [432-1] motion to Modify Protective Order (ft) [Entry date 06/09/03]
- 06/09/2003 440 Letter to Judge Robinson from J. Blumenfeld re follow up on proposed agenda for the conference this afternoon and Smith & Nephew's 6/6 response (ft)
- 06/09/2003 441 COMBINED Reply Brief Filed by ArthroCare Corp. [427-1] motion for Entry of Judgment of no Inequitable Conduct and Answer Brief to Smith & Nephew's counter motion to strike (ft)
- 06/09/2003 = 2nd Part of D.I. # 441; Answer Brief Filed by ArthroCare Corp. [437-1] cross motion to Strike [427-1] motion for Entry of Judgment of no Inequitable Conduct - Reply Brief due 6/16/03 and Reply brief in support of Motion for Jgm of no inequitable conduct; SEE D.I. # 441 for document (ft)
- 06/09/2003 442 Opening brief by Smith & Nephew Inc. in support of its inequitable conduct case (ft) [Entry date 06/10/03]
- 06/09/2003 443 SEALED Declaration of William J. Marsden, Jr. in support of Smith & Nephew's opening brief in support of its inequitable conduct case (D.I. # 442) (ft) [Entry date 06/10/03]
- 06/09/2003 = Tele-conference held; Judge Robinson presiding; crt. rpt. B. Gaffigan; re post-trial briefing (rd) [Entry date 06/11/03]
- 06/10/2003 444 SEALED Steno Notes for 6/9/03 Teleconf.; Judge Robinson presiding; court rpt. B. Gaffigan (ft)
- 06/10/2003 445 Letter to Judge Robinson from K. Jacobs Loudon re reply brief; ArthroCare will not file a reply brief in support of its motion for a permanent injunction (D.I. # 424) pending the filing of post-trial motions (ft) [Entry date 06/11/03]
- 06/10/2003 446 Letter to Clerk from W. Marsden, Jr. enclosing original signature page for Declaration of Dr. Roy A. Majors attached as Exhibit D to D.I. # 436; replace the faxed version previously submitted with the enclosed original (ft) [Entry date 06/11/03]
- 06/11/2003 = Deadline updated; set Oral Argument for 3:30 9/15/03 set in court on 6/9/03 (rd)
- 06/11/2003 447 TRANSCRIPT filed [0-0] telephone conference for dates of 6/9/03; Judge Robinson presiding; Court Rptr. B. Gaffigan (ft)
- 06/11/2003 448 SEALED TRANSCRIPT filed [0-0] telephone conference for dates of 6/9/03; Judge Robinson presiding; court rpt. B. Gaffigan (ft)
- 06/12/2003 = Due to a clerical error, there is no D.I. # 449 (ft) [Entry date 06/20/03]
- 06/16/2003 450 MOTION by Smith & Nephew Inc. with Proposed Order for Alan H. Blankenheimer, Esquire to Appear Pro Hac Vice (ft) [Entry date 06/17/03]
- 06/16/2003 451 Letter to Judge Robinson from W. Marsden, Jr. re post-trial motion practice; Smith & Nephew will not file any further briefing on D.I. # 427 and D.I. # 437; understand these motions are now moot and the parties will brief the issue of inequitable conduct according to the schedule set during the teleconf. (ft) [Entry date 06/17/03]
- 06/18/2003 = So Ordered granting [450-1] motion for Alan H. Blankenheimer, Esquire to

- Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (rd)
- 06/20/2003 452 JUDGMENT for ArthroCare Corp. against Smith & Nephew Inc. (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 06/26/2003 453 Expedited MOTION by Smith & Nephew Inc. with Proposed Order for Leave to extend page limits for briefing on Smith & Nephew's Motion for Jgm. as a matter of law Answer Brief due 7/10/03 re: [453-1] motion (ft)
- 06/27/2003 454 Answer Brief Filed by ArthroCare Corp. [453-1] expedited motion for Leave to extend page limits for briefing on Smith & Nephew's Motion for Jgm. as a matter of law - Reply Brief due 7/7/03 (ft)
- 06/30/2003 = So Ordered denying [453-1] motion for Leave to extend page limits for briefing on Smith & Nephew's Motion for Jgm. as a matter of law (signed by Judge Sue L. Robinson) Notice to all parties. (ft)
- 06/30/2003 455 MOTION by Smith & Nephew Inc. with Proposed Order for New Trial Answer Brief due 7/14/03 re: [455-1] motion (ft) [Entry date 07/01/03]
- 06/30/2003 456 SEALED Opening Brief Filed by Smith & Nephew Inc. [455-1] motion for New Trial (ft) [Entry date 07/01/03]
- 06/30/2003 457 SEALED Declaration of William J. Marsden, Jr. in support of D.I. # 456 (ft) [Entry date 07/01/03]
- 06/30/2003 458 Renewal of MOTION by Smith & Nephew Inc. with Proposed Order for Judgment as a Matter of Law pursuant to Fed R. Civ. P. 50(b) Answer Brief due 7/14/03 re: [458-1] motion (ft) [Entry date 07/01/03]
- 06/30/2003 459 Opening Brief Filed by Smith & Nephew Inc. [458-1] motion for Judgment as a Matter of Law pursuant to Fed R. Civ. P. 50(b) (ft) [Entry date 07/01/03]
- 06/30/2003 460 SEALED Declaration of William J. Marsden, Jr. in support of D.I. # 459 (ft) [Entry date 07/01/03]
- 07/01/2003 461 Letter to Judge Robinson from W. Marsden, Jr. re expedited request to extend the page limits for briefing (ft)
- 07/09/2003 462 Answering Brief by ArthroCare Corp. in opposition to [442-1] Opening Brief in support of its inequitable conduct case (ft) [Entry date 07/10/03]
- 07/11/2003 463 Letter to Clerk from K. Jacobs Loudon enclosing ArthroCare's Corrected answering brief in opposition to Smith & Nephew's Opening brief in support of its inequitable conduct case; Corrected Version of D.I. # 462 (ft) [Entry date 07/15/03] [Edit date 07/15/03]
- 07/18/2003 = Exit final jgm. to Commissioner of Patents and Trademarks, Washington, D.C. (rd) [Entry date 07/21/03]
- 07/24/2003 464 SEALED Reply Brief Filed by Smith & Nephew Inc. in support of its inequitable conduct case (ft)
- 07/24/2003 465 SEALED Declaration of Keith A. Walter, Jr. in support of Smith & Nephew, Inc.'s reply brief in support of its inequitable conduct case (D.I. # 464) (ft)
- 07/30/2003 466 Answer Brief Filed by ArthroCare Corp. [455-1] motion for New Trial - Reply Brief due 8/6/03 (ft) [Entry date 07/31/03]
- 07/30/2003 467 Answer Brief Filed by ArthroCare Corp. [458-1] motion for Judgment as a Matter of Law pursuant to Fed R. Civ. P. 50(b) - Reply Brief due 8/6/03 (ft) [Entry date 07/31/03]
- 08/01/2003 468 Letter to Clerk from J. Blumenfeld enclosing replacement pages to D.I. 466 as they were missing from court's copies (pages 24 & 25) (rd) [Entry date 08/04/03]
- 08/05/2003 469 LETTER to Court from Steven J. Bailick on behalf of deflt. re: a development that relates to one of the issues raised at the 07/08/03 discovery conf. in this case by cnsl. First U.S.A. Bank, N.A. Attached is copy of order dtd. 07/23/03, from Magistrate Judge Howard R. Lloyd of the Northern District of CA granting

- Ms. Whitman's motion to quash FUSA's deposition subpoena. (afb) [Entry date 08/06/03]
- 08/14/2003 470 Reply Brief Filed by Smith & Nephew Inc. [455-1] motion for New Trial (ft) [Entry date 08/15/03]
- 08/14/2003 471 SEALED Declaration of William J. Marsden, Jr. in support of Smith & Nephew's Reply Brief in support of its Motion for New Trial (ft) [Entry date 08/15/03]
- 08/14/2003 472 Reply Brief Filed by Smith & Nephew Inc. [458-1] motion for Judgment as a Matter of Law pursuant to Fed R. Civ. P. 50(b) (ft) [Entry date 08/15/03]
- 08/14/2003 473 Declaration of Eugene B. Joswick in support of Smith & Nephew's Reply Brief in support of its Motion for Jgm as a Matter of Law (ft) [Entry date 08/15/03]
- 09/05/2003 474 Letter to Judge Robinson from W. Marsden, Jr. re oral argument scheduled for 9/15/03 at 3:30 p.m.; pleased to focus argument on any motions or issues of particular interest to the Court; await Court's instructions in that regard as well as amount of time each side will have to present arguments (ft) [Entry date 09/08/03]
- 09/10/2003 = Deadline updated; Motion Hearing set for 4:30 9/15/03 for [458-1] motion for Judgment as a Matter of Law pursuant to Fed R. Civ. P. 50(b), [455-1] motion for New Trial (moved from original time of 3:30 p.m. due to bench trial on same day). (rd)
- 09/11/2003 475 Letter to Judge Robinson from W. Marsden, Jr. re oral argument for 9/15/03 and stating they would like to reserve 20 mins. of their time to address issue of inequitable conduct (D.I. 427, 428, 437, 441, 442, 462, and 464). (rd) [Entry date 09/12/03]
- 09/12/2003 476 MOTION by Smith & Nephew Inc. with Proposed Order for Ruffin B. Cordell to Appear Pro Hac Vice (rd)
- 09/12/2003 = So Ordered granting [476-1] motion for Ruffin B. Cordell to Appear Pro Hac Vice (signed by Judge Sue L. Robinson) Notice to all parties. (rd) [Entry date 09/15/03]
- 09/15/2003 = Motion hearing re: [458-1] motion for Judgment as a Matter of Law pursuant to Fed R. Civ. P. 50(b) Motion hearing held, [455-1] motion for New Trial and re Inequitable Conduct; Judge Robinson presiding; crt. rpt. V. Gunning. (rd) [Entry date 09/16/03]
- 09/24/2003 477 TRANSCRIPT filed [0-0] motion hearing for dates of 9/15/03; Judge Robinson presiding; Court Rptr. V. Gunning (ft)
- 01/14/2004 478 Letter to Judge Robinson from J. Blumenfeld req. conf. with the court to discuss case status and pltf.'s req. for entry of an injunction. (rd) [Entry date 01/15/04]
- 01/16/2004 479 Letter to Judge Robinson from W. Marsden, Jr. responding to D.I. # 478; Smith & Nephew sees no need to hold a status conf. as requested by Arthrocare (ft) [Entry date 01/20/04]
- 01/29/2004 480 ORDER effective immediately the court will not consider applications and requests submitted by letter or in a form other than a motion, absent express approval by the court; no telephone calls are to be made to chambers; emergency matters should be emailed to the court at the address provided with no attachments (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 03/10/2004 481 MEMORANDUM OPINION (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 03/10/2004 482 ORDER granting [429-1] motion to Dismiss Def.'s Antitrust Counterclaim (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 03/10/2004 483 MEMORANDUM OPINION (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 03/10/2004 484 ORDER denying [458-1] motion for Judgment as a Matter of Law pursuant to

Fed R. Civ. P. 50(b), denying [455-1] motion for New Trial, denying [437-1] cross motion to Strike [427-1] motion for Entry of Judgment of no Inequitable Conduct, denying as moot [432-1] motion to Modify Protective Order, granting [427-1] motion for Entry of Judgment of no Inequitable Conduct, granting [424-1] motion for Permanent Injunction (signed by Judge Sue L. Robinson)
copies to: cnsl. (rd)

- 03/11/2004 485 MOTION by ArthroCare Corp. with Proposed Order for Entry of Permanent Injunction Answer Brief due 3/25/04 re: [485-1] motion (ft) [Entry date 03/12/04]
- 03/12/2004 486 MOTION by Smith & Nephew Inc. with Proposed Order to Stay Injunction Answer Brief due 3/26/04 re: [486-1] motion (ft) [Entry date 03/15/04]
- 03/12/2004 487 SEALED Opening Brief Filed by Smith & Nephew Inc. [486-1] motion to Stay Injunction (ft) [Entry date 03/15/04]
- 03/12/2004 488 SEALED MOTION by Smith & Nephew Inc. for Reconsideration of [484-1] order, [482-1] order Answer Brief due 3/26/04 re: [488-1] motion (ft) [Entry date 03/15/04]
- 03/12/2004 489 SEALED Declaration of John Konsin (ft) [Entry date 03/15/04]
- 03/25/2004 490 Objections to ArthroCare's Proposed Form of Injunction attached to ArthroCare's [485-1] motion for Entry of Permanent Injunction, Filed By Smith & Nephew, Inc. - Reply Brief due 4/1/04 (ft)
- 03/26/2004 491 SEALED Answer Brief Filed by ArthroCare Corp. [486-1] motion to Stay Injunction - Reply Brief due 4/2/04 (ft) [Entry date 03/29/04]
- 03/26/2004 492 SEALED Answer Brief Filed by ArthroCare Corp. [488-1] motion for Reconsideration of [484-1] order, [482-1] order - Reply Brief due 4/2/04 (ft) [Entry date 03/29/04]
- 04/01/2004 493 SEALED Reply Brief Filed by ArthroCare Corp. [485-1] motion for Entry of Permanent Injunction (ft) [Entry date 04/02/04]
- 04/02/2004 494 SEALED Reply Brief Filed by Smith & Nephew Inc. [486-1] motion to Stay Injunction (ft) [Entry date 04/05/04]
- 04/02/2004 495 SEALED Declaration of Eugene B. Joswick in support of D.I. # 494 (ft) [Entry date 04/05/04]
- 04/02/2004 496 SEALED Declaration of John Graf (ft) [Entry date 04/05/04]
- 04/06/2004 497 Unopposed MOTION by Smith & Nephew Inc. with Proposed Order to Lift Stay to Permit Smith & Nephew to File an Answering Brief in Opposition to ArthroCare's Motion to Dismiss Smith & Nephew's Antitrust Counterclaim Answer Brief due 4/20/04 re: [497-1] motion (ft) [Entry date 04/07/04]
- 04/06/2004 498 SEALED Supplemental Declaration of Eugene B. Joswick in support of Smith & Nephew's Reply Brief in Support of its Motion to Stay Injunction (ft) [Entry date 04/07/04]
- 04/08/2004 499 ORDER denying as untimely [497-1] motion to Lift Stay to Permit Smith & Nephew to File an Answering Brief in Opposition to ArthroCare's Motion to Dismiss Smith & Nephew's Antitrust Counterclaim (signed by Judge Sue L. Robinson) copies to: cnsl. (rd)
- 04/09/2004 500 NOTICE OF APPEAL by Smith & Nephew Inc. [484-1] order, [483-1] order, [482-1] order, [481-1] order, [452-1] judgment order, [353-1] order; each and every order, opinion, ruling, finding and /or conclusion of the District Court which produced or is subsumed within those portions of such Judgment, Orders, Memorandum Opinions and Memorandum Order, and/or was adverse to Smith & Nephew. Time: 12:40 Fee Status: paid; receipt # 136000 Appeal record due on 5/10/04 (ft) [Entry date 04/12/04]
- 04/14/2004 = Notice of appeal and certified copy of docket to Federal Court of Appeals: [500-1] appeal by Smith & Nephew Inc. (es)
- 04/14/2004 = Copies to the Honorable Sue L. Robinson, Court Reporters, Jack B.

Blumenfeld, William J. Marsden, Jr., and Steven J. Balick (es)

- 04/14/2004 501 Transcript requested [500-1] appeal by Smith & Nephew Inc.; transcript is already on file (ft) [Entry date 04/15/04]
- 04/23/2004 502 NOTICE OF Conditional CROSS-APPEAL by ArthroCare Corp.; conditionally cross appeals from the Court's ruling at trial precluding ArthroCare from offering evidence on infringement under the doctrine of equivalents, the Court's refusal to instruct the jury on infringement under the doctrine of equivalents, and any and all orders, rulings, and judgments underlying these decisions (ft) [Entry date 04/26/04]
- 04/26/2004 503 Transcript requested by ArthroCare Corporation in D.I. # 502 (Notice of Cross Appeals); a transcript is already on file (ft) [Entry date 04/27/04] [Edit date 04/27/04]
- 04/26/2004 = THERE IS NO DI # 504 (ft) [Entry date 04/29/04]
- 04/27/2004 = Cross Notice of appeal and certified copy of docket to Federal Circuit: 502 appeal by ArthroCare (es)
- 04/27/2004 = Copies to the Honorable Sue L. Robinson, Court Reporters, Jack B. Blumenfeld, William J. Marsden, Jr. and Steven J. Balick (es)
- 04/27/2004 505 ORDER; having reviewed D.I. 485 and 490, and the court finding there is sufficient disagreement over the language of the proposed permanent injunction and the implicated infringing products to require additional examination; on or before 4/30/04, Smith & Nephew shall submit its proposed form of permanent injunction; on or before 4/30/04, ArthroCare shall provide reference to the record to show that the products listed in Exhibit A of the proposed permanent injunction are involved in the instant litigation as to the specific claims in dispute (signed by Judge Sue L. Robinson) copies to: cnsi (ft)
- 04/27/2004 506 REVISED ORDER; consistent with the memorandum opinion issued on 3/10/04; granting [429-1] motion to Dismiss Def.'s Antitrust Counterclaims; Defendant/counterclaim plaintiff's antitrust counterclaims are dismissed as to all counterclaim defendants (signed by Judge Sue L. Robinson) copies to: cnsi (ft)
- 04/27/2004 507 MEMORANDUM OPINION (signed by Judge Sue L. Robinson) copies to: cnsi (ft)
- 04/27/2004 508 ORDER denying [488-1] motion for Reconsideration of [484-1] order, [482-1] order, granting in part, denying in part [486-1] motion to Stay Injunction; denied in part as to the stay and granted in part to allow for a 3 month transition period (signed by Judge Sue L. Robinson) copies to: cnsi (ft)
- 04/27/2004 = Deadline updated; set Notice of Compliance deadline to 4/30/04 (ft) [Entry date 04/28/04]
- 04/28/2004 509 REVISED ORDER denying [488-1] motion for Reconsideration of [484-1] order, [482-1] order, granting in part, denying in part [486-1] motion to Stay Injunction (signed by Judge Sue L. Robinson) copies to: cnsi; (Docketing Clerk's note: Original order of 4/27/04 (D.I. # 508) had D.I. # 433 as Motion for Reconsideration; Motion for Reconsideration is D.I. # 488) (ft)
- 04/29/2004 510 Amended NOTICE OF APPEAL by Smith & Nephew Inc. [509-1] order, [508-1] order, [507-1] order, [506-1] order, [499-1] order, [484-1] order, [483-1] order, [482-1] order, [481-1] order, [452-1] judgment order, [353-1] order.; each and every order, opinion, ruling, finding and /or conclusion of the District Court which produced or is subsumed within those portions of such Judgment, Orders, Memorandum Opinions and/or Memorandum Order, and/or was adverse to Smith & Nephew; Time: 11:23 a.m. Appeal record due on 6/1/04 (ft)
- 04/30/2004 511 MOTION by Smith & Nephew Inc. To Delay Entry of Injunction Pending Consideration of Motion to Stay Injunction in the Federal Circuit Answer Brief due 5/14/04 re: [511-1] motion AND Smith & Nephew's Submission of Form of Injunction as Ordered in this Court's Order of 4/27/04 (ft)

- 04/30/2004 512 Submission Concerning the Products Listed in its Proposed Injunction in Response to the Court's 4/27/04 Order by ArthroCare Corp. (ft) [Entry date 05/03/04]
- 05/03/2004 = Amended Notice of appeal and certified copy of docket to Federal Court of Appeals: [510-1] appeal by Smith & Nephew Inc. (es)
- 05/03/2004 = Copies to the Honorable Sue L. Robinson, Court Reporters, Jack B. Blumenfeld, William J. Marsden, Jr. and Steven J Balick (es)
- 05/03/2004 513 ArthroCare's Objections to Smith & Nephew's Form of Injunction and Opposition Filed by ArthroCare Corp. [511-1] motion To Delay Entry of Injunction Pending Consideration of Motion to Stay Injunction in the Federal Circuit - Reply Brief due 5/10/04 (ft)
- 05/03/2004 = NOTICE of Docketing ROA from USCA For the Federal Circuit Re: [500-1] appeal by Smith & Nephew Inc. USCA NUMBER: 04-1323 (ft) [Entry date 05/05/04]
- 05/05/2004 514 Response by Smith & Nephew Inc. to ArthroCare's Submission Concerning the Products Listed in Exhibit A to ArthroCare's Proposed Injunction (ft) [Entry date 05/06/04]
- 05/07/2004 515 Letter to Judge Robinson from W. Marsden, Jr. re waiver of right to file reply in support of motion to delay entry of injunction (D.I. 511) (ft) [Entry date 05/10/04]
- 05/10/2004 = NOTICE of Docketing ROA from USCA for the Federal Circuit Re: [502-1] cross appeal by ArthroCare Corp. USCA NUMBER: 04-1352 (ft) [Entry date 05/11/04]
- 05/11/2004 = Certified and transmitted certified list of docket entries in lieu of record on appeal to U.S. Court of Appeals: [500-1] appeal by Smith & Nephew Inc.; exit certified copies of docket entries indicating record complete for appeal purposes. (es)
- 05/11/2004 = Certified and transmitted certified list of docket entries in lieu of record on appeal to U.S. Court of Appeals: [510-1] appeal by Smith & Nephew Inc.; exit certified copies of docket entries indicating record complete for appeal purposes. (es)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

Civil Action No. 01

DEMAND FOR JURY TRIAL

CLERK OF DISTRICT COURT
DISTRICT OF DELAWARE

JUL 25 2 31 PM '01

FILED

COMPLAINT

Plaintiff ArthroCare Corporation ("ArthroCare"), by and for its Complaint against defendant Smith & Nephew, Inc. ("Smith & Nephew"), alleges as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338(a). Venue lies in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PARTIES

2. Plaintiff ArthroCare is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 595 North Pastoria Avenue, Sunnyvale, California 94086.

3. Defendant Smith & Nephew is a corporation organized and existing under the laws of the State of Delaware with a place of business at 160 Dascomb Road, Andover, Massachusetts 01810.

COUNT ONE

4. ArthroCare hereby realleges and incorporates by reference the allegations of paragraphs 1 through 3 of the Complaint as if fully set forth herein.

5. ArthroCare is the owner of all right, title and interest in United States Patent No. 5,697,536 ("the '536 patent"), entitled "System and Method for Electrosurgical Cutting and Ablation," duly and legally issued on December 16, 1997 to Eggers, et al. A true and correct copy of the '536 patent is attached hereto as Exhibit A.

6. Smith & Nephew, in violation of 35 U.S.C. §§ 271 (a)-(c), has been and is infringing the '536 patent directly, by inducement, and/or contributorily by, among other things, making, using, importing, selling, and/or offering for sale in the United States, without license or authorization, the Dyonics Control RF System.

7. Smith & Nephew's infringement of the '536 patent has been and is willful, and will continue unless enjoined by this Court. ArthroCare has suffered, and will continue to suffer, irreparable injury as a result of Smith & Nephew's infringement. Pursuant to 35 U.S.C. § 284, ArthroCare is entitled to damages for infringement and treble damages. Pursuant to 35 U.S.C. § 283, ArthroCare is entitled to a preliminary and permanent injunction against further infringement.

8. This case is exceptional and, therefore, ArthroCare is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT TWO

9. ArthroCare hereby realleges and incorporates by reference the allegations of paragraphs 1 through 3 of the Complaint as if fully set forth herein.

10. ArthroCare is the owner of all right, title and interest in United States Patent No. 5,697,882 ("the '882 patent"), entitled "System and Method for Electrosurgical Cutting and Ablation," duly and legally issued On December 16, 1997 to Eggers, et al. A true and correct copy of the '882 patent is attached hereto as Exhibit B.

11. Smith & Nephew, in violation of 35 U.S.C. §§ 271 (a)-(c), has been and is infringing the '882 patent directly, by inducement, and/or contributorily by, among other things, making, using, importing, selling, and/or offering for sale in the United States, without license or authorization, the Dyonics Control RF System.

12. Smith & Nephew's infringement of the '882 patent has been and is willful, and will continue unless enjoined by this Court. ArthroCare has suffered, and will continue to suffer, irreparable injury as a result of Smith & Nephew's infringement. Pursuant to 35 U.S.C. § 284, ArthroCare is entitled to damages for infringement and treble damages. Pursuant to 35 U.S.C. § 283, ArthroCare is entitled to a preliminary and permanent injunction against further infringement.

13. This case is exceptional and, therefore, ArthroCare is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT THREE

14. ArthroCare hereby realleges and incorporates by reference the allegations of paragraphs 1 through 3 of the Complaint as if fully set forth herein.

15. ArthroCare is the owner of all right, title and interest in United States Patent No. 6,224,592 ("the '592 patent"), entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," duly and legally issued on May 1, 2001 to Eggers, et al. A true and correct copy of the '592 patent is attached hereto as Exhibit D.

16. Smith & Nephew, in violation of 35 U.S.C. §§ 271 (a)-(c), has been and is infringing the '592 patent directly, by inducement, and/or contributorily by, among other things, making, using, importing, selling, and/or offering for sale in the United States, without license or authorization, the Dyonics Control RF System.

17. Smith & Nephew's infringement of the '592 patent has been and is willful, and will continue unless enjoined by this Court. ArthroCare has suffered, and will continue to suffer, irreparable injury as a result of Smith & Nephew's infringement. Pursuant to 35 U.S.C. § 284, ArthroCare is entitled to damages for infringement and treble damages. Pursuant to 35 U.S.C. § 283, ArthroCare is entitled to a preliminary and permanent injunction against further infringement.

18. This case is exceptional and, therefore, ArthroCare is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, ArthroCare prays for relief as follows:

A. That Smith & Nephew be adjudged to have infringed the '536, '882, and '592 patents;

B. That Smith & Nephew, its officers, agents, servants, employees, attorneys, and those persons in active concert or participation with any of them, be preliminarily and

permanently restrained and enjoined from directly or indirectly infringing the '536, '882, and '592 patents;

C. An accounting for damages by virtue of Smith & Nephew's infringement of the '536, '882, and '592 patents;

D. An award of damages to compensate ArthroCare for Smith & Nephew's infringement, pursuant to 35 U.S.C. § 284, said damages to be trebled because of Smith & Nephew's willful infringement;

E. An assessment of pre-judgment and post-judgment interest and costs against Smith & Nephew, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;


F. That Smith & Nephew be directed to pay ArthroCare's attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

G. That ArthroCare have such other and further relief as this Court may deem just and proper.

JURY DEMAND

ArthroCare demands a trial by jury as to all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL



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July 25, 2001

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

C.A. No. 01-504 SLR

SMITH & NEPHEW, INC.,

Counterclaim-Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim-Defendants.

AMENDED ANSWER AND COUNTERCLAIMS OF SMITH & NEPHEW, INC.

Defendant Smith & Nephew, Inc. ("Smith & Nephew"), answers the correspondingly numbered paragraphs of the complaint of plaintiff ArthroCare Corporation ("ArthroCare") as follows:

JURISDICTION AND VENUE

1. Smith & Nephew admits that ArthroCare's action purports to be one for alleged patent infringement arising under the patent laws of the United States, but Smith & Nephew denies that there has been any such infringement. Smith & Nephew admits that the Court has subject matter jurisdiction over this action. Smith & Nephew further admits that venue is technically proper.

2. Smith & Nephew is without sufficient knowledge or belief as to the truth of the allegations of Paragraph 2 and, on that basis, denies the allegations.

3. Admitted.

COUNT ONE

4. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

5. Smith & Nephew admits that what appears to be a copy of United States Patent No. 5,697,536 (the '536 patent'), entitled "System and Method for Electrosurgical Cutting and Ablation," is attached to the Complaint as Exhibit A. Smith & Nephew admits that the '536 patent issued on December 16, 1997 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 5 and, on that basis, denies them.

6. Denied.

7. Denied.

8. Denied.

COUNT TWO

9. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

10. Smith & Nephew admits that what appears to be a copy of United States Patent No. 5,697,882 ("the '882 patent"), entitled "System and Method for Electrosurgical Cutting and Ablation," is attached to the Complaint as Exhibit B. Smith

& Nephew admits that the '882 patent issued on December 16, 1997 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10 and, on that basis, denies them.

11. Denied.

12. Denied.

13. Denied.

COUNT THREE

14. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

15. Smith & Nephew admits that what appears to be a copy of United States Patent No. 6,224,592 ("the '592 patent"), entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," is attached to the Complaint as Exhibit C (referenced as Exhibit D in the Complaint). Smith & Nephew admits that the '592 patent issued on May 1, 2001 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15 and, on that basis, denies them.

16. Denied.

17. Denied.

18. Denied.

RELIEF REQUESTED BY ARTHROCARE

19. Smith & Nephew requests that the Court grant none of the relief requested by ArthroCare.

AFFIRMATIVE DEFENSES

**FIRST AFFIRMATIVE DEFENSE
(Non-Infringement)**

20. Smith & Nephew does not infringe and has not infringed, either directly, by inducing others to infringe, or by contributing to the infringement by others, any valid claim of the '536, '882 or '592 patents.

**SECOND AFFIRMATIVE DEFENSE
(Invalidity)**

21. The '536, '882 and '592 patents are each invalid because each fails to comply with the requirements of 35 U.S.C. § 101 et seq., including without limitation, Sections 102, 103 and 112.

**THIRD AFFIRMATIVE DEFENSE
(Misuse)**

22. The '536, '882, and '592 patents are each unenforceable for misuse, since, upon information and belief, ArthroCare filed this lawsuit knowing that each patent was invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

**FOURTH AFFIRMATIVE DEFENSE
(Unenforceability Based on Inequitable Conduct)**

23. The '592 patent is unenforceable based on inequitable conduct committed by ArthroCare, the applicants, and/or their attorneys during the prosecution in the United States Patent and Trademark Office ("USPTO") as set forth more fully in paragraphs 15-26 of Smith & Nephew's Counterclaim for a Declaratory Judgment of Non-Infringement.

Invalidity and Unenforceability.

FIFTH AFFIRMATIVE DEFENSE
(Unclean Hands)

24. ArthroCare is entitled to no relief since it comes into this Court with unclean hands since it has misused the '536, '882, and '592 patents and obtained the '592 patent through inequitable conduct.

SMITH & NEPHEW'S COUNTERCLAIMS
AGAINST ARTHROCARE

For its counterclaims against ArthroCare, Smith & Nephew alleges as follows:

JURISDICTION AND VENUE

1. These counterclaims are brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, Title 35 U.S.C., for a declaratory judgment that the '536, '882 and '592 patents are invalid and have not been infringed by any act of Smith & Nephew, and that the '592 patent is unenforceable.

2. ArthroCare has stated that it is a Delaware corporation with its principal place of business at 595 North Pastoria Avenue, Sunnyvale, California.

3. Smith & Nephew is a Delaware corporation with its principal place of business at 1450 Brooks Road, Memphis, Tennessee.

4. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338, 2201 and 2202. An actual and justiciable controversy exists between ArthroCare and Smith & Nephew as to the infringement and validity of the '536, '882 and '592 patents, and enforceability of the '592 patent, as evidenced by ArthroCare's Complaint in this action and Smith & Nephew's Answer to that Complaint, set forth above.

5. Venue is technically proper in this Court under 28 U.S.C. § 1391, and because ArthroCare has brought its Complaint for alleged infringement of the '536, '882 and '592 patents in this Court.

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT,
INVALIDITY AND UNENFORCEABILITY**

6. Smith & Nephew repeats and realleges the allegations of Paragraphs 1-5, above, as if fully set forth herein.

7. On December 16, 1997, the '536 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '536 patent.

8. On December 16, 1997, the '882 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '882 patent.

9. On May 1, 2001, the '592 patent, entitled "System and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '592 patent.

10. Smith & Nephew has not and does not infringe any valid claim of the '536, '882 or '592 patents.

11. The '536, '882 and '592 patents are each invalid because each fails to comply with the requirements of 35 U.S.C. § 101 *et seq.*, including without limitation, Sections 102, 103 and 112.

12. The '536, '882, and '592 patents are each unenforceable for misuse, since, upon information and belief, ArthroCare filed this lawsuit knowing that each patent was invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

13. ArthroCare is entitled to no relief since it comes into this Court with unclean hands since it has misused the '536, '882, and '592 patents and obtained the '592 patent through inequitable conduct.

14. The '592 patent is unenforceable based on inequitable conduct during prosecution of the '592 patent in the USPTO, as more particularly set forth below.

ArthroCare's Deceptive Activities In the Patent Office

15. On or about February 23, 1998, ArthroCare filed suit against Ethicon, Inc., *et al.*, in the U.S. District Court for the Northern District of California ("the California Court"), alleging infringement of four of its patents for electrosurgery devices and methods, including the '536 and '882 patents at issue in this action. That case was before Senior Judge William H. Orrick and was captioned *ArthroCare Corp. v. Ethicon, Inc.*, Civil Action No. 98-CV-609 ("the first ArthroCare case").

16. During the course of the first ArthroCare case, the California Court made extensive and detailed pretrial rulings, including a 33 page opinion dated on or about December 2, 1998 in which, among other things, it reviewed and interpreted 17 prior art references in the field of electrosurgery.

17. Significantly, in regard to one prior art reference, U.S. Patent No. 4,116,198 ("the Roos '198 reference"), there was a dispute between the parties as to whether the reference taught the use of an electrically conductive fluid in order to create a current flow between the active and return electrodes.

18. The California Court expressly found that the use of such a conductive fluid was explicitly described in claim 1 of the Roos '198 reference.

19. Upon information and belief, while the first ArthroCare case was pending, ArthroCare applied for the '592 patent, which then issued following the conclusion of that case.

20. During the prosecution of the application for the '592 patent, ArthroCare, the applicants and their attorney(s) were under a duty of candor and good faith in dealing with the USPTO, which included a duty to disclose to the USPTO all information material to patentability.

21. Upon information and belief, ArthroCare, the applicants and/or their attorney(s) violated their duty of candor and good faith and disclosure owed to the USPTO.

22. Upon information and belief, during the prosecution of the application for the '592 patent in the USPTO, neither ArthroCare, the applicants nor their attorney(s) complied with the Manual of Patent Examining Procedure § 2001.06(c) requiring the disclosure of material information arising from litigation concerning the subject matter for which a patent is being sought. For example, neither ArthroCare, the applicants nor their attorney(s) told the patent examiner that the Roos '198 reference disclosed the use of conductive fluid in claim 1 or that the California Court had specifically found that it had.

23. Instead, ArthroCare, the applicants and/or their attorney(s), submitted a supplemental information disclosure statement on or about October 25, 1999 in which they simply listed the California Court's December 2, 1998 opinion in a list of 84 pleadings that had been filed in the first ArthroCare case, but never submitted a copy of the opinion to the USPTO.

24. Further, during the prosecution of the application for the '592 patent, in an Office Action mailed on or about February 29, 2000, the patent examiner inferred that the Roos '198 device must inherently have used conductive fluid in order to work,

and as a result rejected certain claims of the application under 35 U.S.C. § 102(b) as being clearly anticipated by the Roos '198 reference.

25. In an Amendment filed in the USPTO on or about May 30, 2000, ArthroCare, the applicants and/or their attorney(s) responded to the patent examiner's rejection by making the misleading argument that Roos '198 device did not use conductive fluid. ArthroCare failed to inform the patent examiner of the California Court's decision that Claim 1 of the Roos '198 reference explicitly disclosed a conductive fluid. ArthroCare thus withheld material information and made affirmative misrepresentations concerning the Roos '198 patent.

26. Accordingly, the '592 patent is unenforceable due to inequitable conduct since, upon information and belief, ArthroCare, the applicants and/or their attorney(s) intentionally misrepresented and withheld material information from the USPTO with an intent to deceive the USPTO into issuing the '592 patent.

COUNTERCLAIM FOR ANTITRUST VIOLATIONS

27. Paragraphs 1-26 are incorporated herein by reference.

28. This counterclaim is for antitrust violations under 15 U.S.C. §1. This Court has jurisdiction over the subject matter of this counterclaim under the provisions of Federal Rules of Civil Procedure 13 and 19.

CONFIDENTIAL INFORMATION HAS
BEEN REMOVED FROM THIS PAGE

PRAAYER FOR RELIEF

WHEREFORE, Smith & Nephew prays that judgment be entered in its favor and against ArthroCare granting Smith & Nephew the following:

- A. That ArthroCare take nothing by this action;
- B. A declaration that Smith & Nephew does not infringe and has not infringed any claim of the '536 patent, the '882 patent or the '592 patent;
- C. A declaration that the '536, '882 and '592 patents are invalid;
- D. A declaration that the '536, '882 and '592 patents are unenforceable;
- E. An injunction enjoining ArthroCare, its officers, agents, servants, employees, and attorneys and those persons in active concert or participation with them who receive actual notice of this judgment, from directly or indirectly charging infringement, or instituting any action for infringement, of the '536 patent, '882 patent or '592 patent against Smith & Nephew or any of its customers, licensees, or suppliers;
- F. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285;

- G. An award to Smith & Nephew of all its costs, expenses and attorneys' fees in this action;

- I. An award to Smith & Nephew of such other and further relief as the Court deems just and proper.

JURY DEMAND

Smith & Nephew demands trial by jury on all issues triable of right by a jury.

Dated: July 30, 2002

30 July 2002 FISH & RICHARDSON, P.C.

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CHARGE TO THE JURY

ARTHROCARE CORPORATION

v.

SMITH & NEPHEW, INC.

Civil Action No. 01-504-SLR

ROBINSON, C. J.

A 314

MAY 9, 2003

GENERAL INFORMATION

INTRODUCTION

Members of the jury:

Now it is time for me to instruct you about the law that you must follow in deciding this case. I will start by explaining your duties and the general rules that apply in every civil case. I will explain some rules that you must use in evaluating particular testimony and evidence. Then I will explain the positions of the parties and the law you will apply in this case. And last, I will explain the rules that you must follow during your deliberations in the jury room and the possible verdicts that you may return. Please listen very carefully to everything I say.

JURORS' DUTIES

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way.

Your second duty is to take the law that I give you and apply it to the facts and decide, under the appropriate burden of proof, which party should prevail. I will instruct you as to the required burdens of proof shortly. It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not let any bias, sympathy or prejudice that you may feel toward one side or the other influence your decision in any way.

EVIDENCE DEFINED

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence in this case includes only what the witnesses said while they were testifying under oath, the exhibits that I allowed into evidence, and the stipulations to which the lawyers agreed.

Nothing else is evidence. Counsel's closing arguments are not evidence; counsel were simply given the opportunity to summarize and interpret the evidence for you. It is your recollection of the facts, not the lawyers' recollections, that must govern your deliberations. The lawyer's questions and objections are not evidence. My legal rulings are not evidence. Any of my comments and questions are not evidence.

During the trial I may not have let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. You must completely ignore all of these things. Do not even think about them. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not evidence, and you are bound by your oath not to let them influence your decision in any way.

Make your decision based only on the evidence, as I have defined it here, and nothing else.

CONSIDERATION OF EVIDENCE

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

DIRECT AND CIRCUMSTANTIAL EVIDENCE

Now, some of you may have heard the terms ~~direct~~ evidence and ~~circumstantial~~ evidence. Direct evidence is simply evidence like the testimony of an eyewitness which, if you believe it, directly proves a fact. If a witness testified that he saw it raining outside, and you believed him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

CREDIBILITY OF WITNESSES

You are the sole judges of the credibility of the witnesses. In considering the testimony of any witness, you may take into account the witnesses' abilities, education, opportunities to observe, age, memory, manner while testifying, any interest, bias or prejudice shown, and the reasonableness of the testimony considered in light of all the evidence in the case.

During the examination of a witness, you may have heard discussions about ~~the~~ impeachment. Impeachment of a witness, whether a fact witness or an expert witness, occurs when his or her testimony is contradicted by other evidence. When you decide how much weight to give to the testimony of a witness, you may consider any contradiction of the witness's testimony demonstrated through impeachment.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact, or, whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was simply an innocent lapse of memory or an

intentional falsehood, and that may depend upon whether it concerns an important fact or an unimportant detail.

EXPERT WITNESSES

When knowledge of technical subject matter may be helpful to a jury, a person who has special training or experience in that technical field is called an expert witness is permitted to state his or her opinion on those technical matters. However, you are not required to accept that opinion. As with any other witness, it is up to you to judge the credentials and credibility of the expert witness and decide whether to rely upon his or her testimony.

DEPOSITION TESTIMONY

Some of the witnesses that testified appeared here in court. Others testified through depositions that were either read in court or played on videotape. You should afford any testimony given by deposition the same consideration you would give it had the witness personally appeared in court. Like the testimony of a live witness, the statements made in a deposition are made under oath and are considered evidence which may be used to prove particular facts.

NUMBER OF WITNESSES

One more point about the witnesses. Sometimes jurors wonder if the number of witnesses who testified makes any difference. Do not make any decisions based only on the number of witnesses who testified. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

DEMONSTRATIVE EXHIBITS

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. You will have these admitted exhibits in the jury room for your deliberations. The remainder of the exhibits (including charts and animations) were offered to help illustrate the testimony of various witnesses. These illustrative exhibits, called demonstrative exhibits, have not been admitted, are not evidence, and should not be considered as evidence. Rather it is the underlying testimony of the witness that you heard and the documents that were admitted into evidence when you saw the demonstrative exhibits that is the evidence in the case.

BURDENS OF PROOF

This is a civil case in which the plaintiff, ArthroCare, is charging the defendant, Smith & Nephew, with patent infringement.

ArthroCare has the burden of proving patent infringement by what is called a preponderance of the evidence. That means that ArthroCare has to produce evidence which, when considered in light of all of the facts, leads you to believe that what ArthroCare claims regarding infringement is more likely true than not. To put it differently, if you were to put ArthroCare's and Smith & Nephew's evidence on the issue of infringement on the opposite sides of a scale, the evidence supporting ArthroCare's claims of infringement would have to make the scales tip somewhat on its side.

In this case, Smith & Nephew contends that the claims of ArthroCare's patents are invalid. A patent, however, is presumed to be valid. Because of the presumption that a patent is valid, Smith & Nephew has the burden of proving that the asserted claims are invalid by clear and convincing evidence. Clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is thus a higher burden than proof by a preponderance of the evidence.

Those of you who are familiar with criminal cases will have heard the term ~~the~~ proof beyond a reasonable doubt. That burden does not apply in a civil case and you, therefore, should put it

out of your mind in considering whether or not ArthroCare or
Smith & Nephew has met its burden of proof.

THE PARTIES AND THEIR CONTENTIONS

THE PARTIES

The plaintiff ArthroCare is the owner of U.S. Patent Nos. 5,697,536, 5,697,882, and 6,224,592 B1, which are the patents asserted in this case. I will refer to these patents as the § 536 patent, § the § 882 patent, § or the § 592 patent, § respectively, or as the patents-in-suit. The named inventors of the patents-in-suit are Philip Eggers and Hira Thapliyal, who assigned the patents-in-suit to ArthroCare. ArthroCare has the exclusive rights to make, use, sell, and offer for sale any product, apparatus, system, or method that is covered by the patents-in-suit.

The defendant Smith & Nephew has marketed a number of medical devices called the ElectroBlade, Saphyre and Control RF. ArthroCare has accused these products and their use of infringement in this case. I may refer to these devices collectively as the § Smith & Nephew accused products. §

ARTHROCARE'S CONTENTIONS

ArthroCare contends that Smith & Nephew literally infringes claims 46, 47 and 56 of the '536 patent, claims 13, 17 and 54 of the '882 patent and claims 1, 3, 4, 11, 21, 23, 26, 27, 32 and 42 of the '592 patent, by making, using, selling and offering for sale in the United States the Smith & Nephew accused products and by contributing to and inducing the infringement of these claims by others. These claims are called the ~~§~~asserted claims.~~§~~

SMITH & NEPHEW'S CONTENTIONS

Smith & Nephew contends that it does not infringe the asserted claims and that they are invalid and unenforceable.

Smith & Nephew contends that the asserted claims of the patents-in-suit are invalid because, based on the prior art, they were anticipated at the time of the alleged invention.

Smith & Nephew further contends that claims 13, 17, and 54 of the '882 patent are invalid because the '882 patent does not teach one of ordinary skill how to practice these claims without undue experimentation. Smith & Nephew contends that claims 46, 47, and 56 of the '536 patent, claim 17 of the '882 patent, and claim 42 of the '592 patent are invalid because the patents do not contain complete written descriptions of the inventions. Finally, Smith & Nephew contends that claim 47 of the '536 patent and the asserted claims of the '592 patent are invalid because they are not definite enough that a skilled person reading them knows what is covered by the claims, and what is not.

SUMMARY OF PATENT ISSUES

In this case, you must decide several things according to the instructions that I shall give you. They are:

1. As to each of the asserted claims of the patents-in-suit, whether ArthroCare has shown by a preponderance of the evidence that Smith & Nephew has literally infringed that claim.
2. As to each of the asserted claims, whether Smith & Nephew has proven by clear and convincing evidence that the claim is invalid.

INFRINGEMENT

PATENT INFRINGEMENT - GENERALLY

The patent law provides that any person or business entity which makes, uses, offers for sale or sells, without the patent owner's permission, a product or method legally protected by at least one claim of a valid patent, within the United States, infringes the patent.

There are three ways to infringe a patent. One may: (1) directly infringe a patent; (2) induce others to infringe a patent; or (3) contribute to the infringement of a patent. I will explain each type of infringement more completely in a moment.

A patent owner may enforce its right to exclude others from making, using, selling or offering for sale the patented invention by filing a lawsuit for patent infringement. A patent confers on its owner an exclusive property right in the patented invention.

Here, ArthroCare, the patent owner, has sued Smith & Nephew and has alleged that Smith & Nephew directly infringes the asserted claims of the patents-in-suit. Additionally, ArthroCare alleges that Smith & Nephew has induced and contributed to the infringement of the asserted claims of the patents-in-suit. Smith & Nephew denies such infringement.

THE ASSERTED CLAIMS

To decide whether Smith & Nephew has infringed the patents-in-suit, you will have to look to the ~~claims~~ of the patents-in-suit that have been asserted. The patent claims are the numbered paragraphs at the end of each patent.

The purpose of the claims is to provide notice to the public of what a patent covers and does not cover. The claims define the boundaries of the invention described and illustrated in the patent and the patent owner's property rights. Infringement is the act of trespassing on those rights. Only the claims of the patent can be infringed. Neither the specification, which is the written description of the invention, nor the drawings of the patent can be infringed.

Not every claim of a patent must cover every feature of the patented invention. Each claim is a separate statement of the patented invention and, therefore, each of the asserted claims must be considered individually. To show infringement of a particular patent, a plaintiff such as ArthroCare need only establish that one of the asserted claims in that patent has been infringed.

There are a number of claims involved here. ArthroCare asserts that Smith & Nephew infringes claims 46, 47 and 56 of the '536 patent, claims 13, 17 and 54 of the '882 patent and claims 1, 3, 4, 11, 21, 23, 26, 27, 32 and 42 of the '592 patent. Claim 46 of the '536 patent begins at column 18, line 29 of the '536 patent, which is Plaintiff's Exhibit No. 1 in evidence. The

other asserted claims of the '536 patent are found in columns 18 and 19 of the '536 patent. Claim 13 of the '882 patent begins at column 24, line 54 of the '882 patent which is Plaintiff's Exhibit No. 2 in evidence. The other asserted claims of the '882 patent are found in columns 24 and 25 of the '882 patent. Claim 1 of the '882 patent, from which claims 13, 17 and 54 depend, has been corrected by certificates of correction. Claim 1 of the '592 patent begins at column 24, line 6 of the '592 patent, which is Plaintiff's Exhibit No. 3 in evidence. The other asserted claims of the '592 patent are found in columns 24 through 26 of the '592 patent.

LITERAL INFRINGEMENT

In this case, Arthrocare contends that Smith & Nephew's accused products and methods literally infringe the asserted claims. In order to prove that any one of the asserted claims is literally infringed, Arthrocare must prove by a preponderance of the evidence that Smith & Nephew's accused products or methods include each and every limitation of that particular claim. In other words, you must compare the features of the accused products or methods with the limitations of each asserted claim in order to determine whether the accused products or methods include each and every limitation of an asserted claim.

With respect to the asserted claims of the '592 and '882 patents, it does not matter whether the accused methods practice the invention of any asserted method claim, so long as Arthrocare has proven by a preponderance of the evidence that the accused methods operate in a way that meet each and every step of the method described in the claim some of the time.

INDEPENDENT AND DEPENDENT CLAIMS

There can be two different types of claims in a patent. The first type is called an independent claim. An independent claim does not refer to any other claim of the patent. An independent claim is read by itself to determine its scope. Claim 45 of the '536 patent, claim 1 of the '882 patent, and claims 1 and 23 of the '592 patent are independent claims. You know this because these claims mention no other claim. Accordingly, the words of these claims are read by themselves in order to determine what the claims cover.

On the other hand, a dependent claim is a claim that refers to at least one other claim in the patent and thus incorporates whatever the other claim says. Accordingly, to determine what a dependent claim covers, you must read both the dependent claim and the independent claim to which it refers.

In this case, for example, claim 46 of the '536 patent is a dependent claim -- it depends from claim 45. Accordingly, the words of claim 45 and claim 46 must be read together in order to determine what the dependent claim, claim 46, covers.

Some claims of the patents-in-suit are broader than other claims. You are not to read the limitations or words of a narrower or dependent claim into a broader or independent claim if the broader claim does not explicitly contain the same limitations.

CONSTRUCTION OF CLAIMS

It is my duty under the law to define what the patent claims mean. I have made my determination on the meaning of each claim. I will now instruct you on the meaning of several of the terms and phrases in the patent claims that are at issue in this case. The meanings I give you should be interpreted by you in accordance with their plain meanings. Except where the court has directed otherwise, all other claim language should be interpreted in accordance with its ordinary and accustomed meaning.

You are advised that the following definitions for the following terms must be applied:

1. "Connector."

The court shall apply the ordinary definition of the word "connector." The word connect means "to bind or fasten together; join or unite; link." The word ~~connector~~ in terms of the '536 patent, shall be construed to mean ~~a~~ structure that electrically links the electrode terminal to the high frequency power supply.

2. "Electrically Conducting Fluid Supply."

Consistent with the prosecution history, the phrase ~~electrically conducting fluid supply~~ shall be construed to mean ~~a~~ medical container that stores electrically conducting fluid. An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline.

3. "Spacing a Return Electrode Away From the Body Structure" and "the Return Electrode is Not in Contact with the Body Structure."

The claim limitation ~~the~~ the return electrode is not in contact with the body structure~~is~~ is clear -- the return electrode is not to contact the body at all during the performance of the claimed method. The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed.

4. "Electrically Conducting Fluid" and "Electrically Conductive Fluid."

Consistent with the ordinary definition, ~~electrically~~ electrically conducting fluid~~and electrically~~ electrically conductive fluid~~shall be~~ shall be construed to mean ~~any~~ any fluid that facilitates the passage of electrical current. Examples of electrically conducting fluids are blood and saline.

5. "Directing or Delivering the Electrically Conductive Fluid to the Target site."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

6. "Electrode Terminal."

Consistent with the intrinsic evidence of the patents in suit, ~~electrode terminal~~ electrode terminal means ~~one or more~~ one or more active electrodes.

7. "Active Electrode."

The court shall apply the ordinary definition of the term ~~active electrode~~ active electrode in the relevant art. The term "active electrode" means ~~a~~ a stimulating electrode . . . applied to tissue

for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.⌘

8. "Return Electrode."

As contrasted with an active electrode, the term ⌘return electrode⌘ means ⌘an electrode having a larger area of contact than an active electrode, thus affording a lower current density.⌘

9. "Insulating Member."

The court shall apply the ordinary definition of the phrase "insulating member." Thus, the phrase ⌘insulating member⌘ shall be construed to mean ⌘a member which provides a high degree of resistance to the passage of charge.⌘

10. "500 to 1400 Volts Peak to Peak."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

11. "Through the Region of the Target Site."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

12. "Immersing."

The court shall apply the ordinary definition of the term "immersing." The term ⌘immersing⌘ shall be construed to mean ⌘to plunge into or place under a fluid[.]⌘

13. "Electrosurgical System."

The court shall apply the ordinary definition of the term "system." The term ~~system~~ shall be construed to mean ~~an~~ assemblage or combination of things or parts forming a unitary whole[.]

14. "Distal End" and "Proximal End."

The court shall apply the ordinary definition of the term "distal" and "proximal." The term ~~distal end~~ shall be construed to mean ~~the~~ end situated away from the point of origin or attachment. The term ~~proximal end~~ shall be construed to mean ~~the~~ end situated toward the point of origin or attachment.

OPEN-ENDED OR "COMPRISING" CLAIMS

The asserted claims of ArthroCare's patents-in-suit use the transitional phrase ~~comprising~~ or ~~comprises~~. ~~Comprising~~ or ~~comprises~~ is interpreted the same as ~~including~~ or ~~containing~~. In a patent claim, comprising means that the claim is open-ended. As such, the claim is not limited to only what is in the claim. Based on this explanation, if you find that Smith & Nephew's accused products or methods include all of the limitations in any of the asserted claims, the fact that the products or methods may also include additional features or elements is irrelevant. The presence of additional features or elements in Smith & Nephew's products or methods does not mean that they do not infringe an asserted claim.

Certain claims use the language ~~consisting essentially of~~ certain components. In interpreting patent claims, these words do not mean the same thing as ~~comprising~~, ~~including~~, or ~~containing~~. Rather a claim including the language ~~consisting essentially of~~ will be infringed only if you find that any components added by defendant beyond those in the claim(s) do not materially affect the basic and novel characteristics of the invention claimed in the plaintiff's patent.

DIRECT INFRINGEMENT

For each of the patents-in-suit, Smith & Nephew is liable for directly infringing that patent if you find that ArthroCare has proven by a preponderance of the evidence that Smith & Nephew has made, used, sold, or offered for sale the invention defined in at least one of the asserted claims of the patent.

KNOWLEDGE OF PATENT OR INTENT TO INFRINGE IS IMMATERIAL

Smith & Nephew is liable for directly infringing the patents-in-suit in this case if you find that ArthroCare has proven by a preponderance of the evidence that Smith & Nephew has made, used, offered for sale or sold the invention defined in at least one asserted claim of the patents-in-suit.

A company can infringe a patent without knowing that what it is doing is an infringement of the patent. It may also infringe a patent even though it believes in good faith that what it is doing is not an infringement of the patent.

INDIRECT INFRINGEMENT

As I have told you, in addition to direct infringement, there are two types of indirect infringement ~~§~~ induced infringement and contributory infringement. The act of encouraging or inducing others to infringe a patent is called ~~§~~inducing infringement.~~§~~ The act of contributing to the infringement of others is called ~~§~~contributory infringement.~~§~~

INDUCING INFRINGEMENT

A person induces patent infringement if he or she purposefully causes, urges or encourages another to infringe a patent. Inducing infringement cannot occur unintentionally. This is different from direct infringement, which, as I've just told you, can occur unintentionally. In order to prove inducement, the patent owner must prove that it is more likely true than not that the accused inducer knew of the patent and encouraged or instructed another person to perform a process in a manner that infringes the patent. The patent owner must also prove that it is more likely true than not that the other person infringed the patent. A person can be an inducer even if he or she thought that what he or she was encouraging or instructing the other person to do was not an infringement.

ArthroCare asserts that Smith & Nephew induced patent infringement. ArthroCare must prove four things by a preponderance of the evidence:

First, Smith & Nephew encouraged or instructed another person how to perform a process in a manner that you, the jury, find infringes the ArthroCare patent claims;

Second, Smith & Nephew knew of ArthroCare's patents;

Third, Smith & Nephew knew or should have known that its encouragement or instructions would likely result in the other person doing that which you find to be a direct infringement of the ArthroCare patents;

Fourth, the other person infringed the ArthroCare patents.

Smith & Nephew cannot be liable for inducing infringement unless an asserted claim has been directly infringed by another. However, proof of inducing infringement and the underlying direct infringement may be based on circumstantial evidence you have heard in this case. Direct evidence of infringement and contributory infringement is not required.

CONTRIBUTORY INFRINGEMENT

In this case, ArthroCare asserts that Smith & Nephew is contributing to the infringement of the ArthroCare patents. In order to establish that Smith & Nephew has contributorily infringed ArthroCare's patents, ArthroCare must prove five things by the more likely than not standard. These five things are:

First, Smith & Nephew knew of ArthroCare's patents;

Second, the accused products or methods perform a material part of the claimed inventions and Smith & Nephew sold or supplied those products or methods;

Third, Smith & Nephew knew that the products or methods were especially made for use in a manner that infringes the patent claims;

Fourth, the products or methods are not staple or commodity articles;

Fifth, the products or methods were actually used in a manner that you find infringes the ArthroCare patents.

Smith & Nephew cannot be liable for contributory infringement unless an asserted claim has been directly infringed by another. However, proof of contributory infringement and the underlying direct infringement may be based on circumstantial evidence you have heard in this case. Direct evidence of infringement and contributory infringement is not required.

VALIDITY DEFENSES

PRESUMPTION OF VALIDITY

The granting of a patent by the Patent Office carries with it the presumption that the patent is valid. From issuance of the patent, it is presumed that the subject matter of the patent is new and useful, and constitutes an advance which was not, at the time the invention was made, obvious to one of ordinary skill in the art. The law presumes, in the absence of clear and convincing evidence to the contrary, that the Patent Office acted correctly in issuing the patent.

Because a patent is presumed valid, Smith & Nephew bears the burden of proving invalidity by clear and convincing evidence. Although this presumption can be rebutted, the burden is on Smith & Nephew to do so. Smith & Nephew can only overcome the presumption of validity with facts establishing invalidity by clear and convincing evidence.

Each of the asserted claims of ArthroCare's patents is presumed valid independently of the validity of any other claim. This is because each claim of a patent defines a separately patentable invention. Dependent claims are presumed valid even though they may be dependent upon a claim which is proven invalid. Smith & Nephew, therefore, must prove the invalidity of each claim by clear and convincing evidence.

AFFIRMATIVE DEFENSE OF INVALIDITY GENERALLY

Smith & Nephew has challenged the validity of the asserted claims on a number of grounds. First, Smith & Nephew contends that the asserted claims of the patents in suit are not new, but are contained in the prior art. Smith & Nephew also contends that certain of the asserted claims are not adequately described or do not adequately teach one of ordinary skill in the art how to practice the claimed invention.

ANTICIPATION

A person cannot obtain a patent on an invention if someone else has already made the same invention. In other words, the invention must be new. If an invention is not new, we say that it was ~~anticipated~~ by the prior art. An invention that is ~~anticipated~~ by the prior art is not entitled to patent protection. A party challenging the validity of a patent must prove anticipation by clear and convincing evidence.

In this case, the prior art asserted against the patents in suit includes patents that issued one year before the effective filing date, publications having a publication date one year before the effective filing date, and U.S. Patents, to wit:

The Roos `198 patent (DTX 11)

Article by E. Elsässer and E. Roos (DTX 59A, 59B)

The Pao `499 patent (DTX 21)

The Doss `007 patent (DTX 17)

The Manwaring `138 patent (DTX 46)

Article by C. Slager et al. (DTX 65)

The Roos `198 patent is asserted against claims 45, 46, 47 and 56 of the `536 patent and claims 1, 3, 4, 23, 26, and 27 of the `592 patent.

The article by E. Elsässer and E. Roos is asserted against claims 45, 46, 47 and 56 of the `536 patent and claims 1, 3, 4, 23, 26, and 27 of the `592 patent.

The Pao `499 patent is asserted against claims 45, 46, and 56 of the `536 patent.

The Doss `007 patent is asserted against claims 45, 46, and 47 of the `536 patent and claims 1, 3, 4, 11, and 21 of the `592 patent.

The Manwaring `138 patent is asserted against claims 1, 13, and 54 of the `882 patent.

The article by C. Slager et al. is asserted against claims 1, 13, 17 and 54 of the `882 patent and claims 1, 3, 11, 21, 23, 26, 32, and 42 of the `592 patent.

For an asserted patent claim to be anticipated by such prior art, each and every limitation of the claim must be present within a single item of prior art, whether that prior art is a publication or a prior patent. You may not find that the prior art anticipates a patent claim by combining two or more items of prior art.

There must be no difference between the limitations of the asserted claims and the features of the prior art. A prior art disclosure that almost meets the claim does not anticipate. The prior art reference also must describe the invention with sufficient detail to establish that the subject matter existed in the prior art. Also, in order to anticipate, the prior art must enable one skilled in the art to practice the invention such that it is available to the public.

There cannot be an accidental or unrecognized anticipation. A prior duplication of the claimed invention that was accidental, or unrecognized, unappreciated and incidental to some other purpose is not an invalidating anticipation.

In deciding whether a single item of prior art anticipates a patent claim, you should consider both that which is expressly stated or present in the item of prior art, and also that which is inherently present. Something is inherent in an item of prior art if it is always present in the prior art or always results from the practice of the prior art, and if a person with ordinary skill in the art would understand that to be the case.

ENABLEMENT

The Patent Laws also require that the disclosure of a patent be sufficiently detailed to enable those skilled in the art to practice the invention. Smith & Nephew has alleged that claims 13, 17, and 54 of the '882 patent do not satisfy the enablement requirement. The purpose of the enablement requirement is to ensure that the public, in exchange for the patent rights given to the inventor, obtains from the inventor a full disclosure of how to practice the claimed invention. However, because descriptions in patents are addressed to those skilled in the art to which the invention pertains, an applicant for a patent need not expressly set forth in his specification subject matter which is commonly understood by persons skilled in the art.

The law does not require that an applicant describe in his specification every conceivable and possible future embodiment of the invention. The enablement requirement is met if the description enables any mode of making and using the claimed invention. The fact that some experimentation may be required for a skilled person to practice the claimed invention does not mean that a patent's written description does not meet the enablement requirement. Enablement is not precluded by the necessity for some experimentation such as routine screening. In fact, a considerable amount of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. In other words, a

written description is enabling so long as undue experimentation is not necessary.

In determining whether undue experimentation is needed you should weigh a number of factors, including: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in that art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. A permissible amount of experimentation is that amount that is appropriate for the complexity of the field of invention and for the level of expertise and knowledge of persons in that field.

LEVEL OF ORDINARY SKILL

The person of ordinary skill is not the inventor but rather a hypothetical person who is presumed to be aware of all the prior art at the time of the invention.

In this case, a person of ordinary skill is someone with a Bachelor's degree in electrical engineering, physics, mechanical engineering or medical sciences and experience with the design, development, operation, and evaluation of RF-powered electrosurgical devices for clinical applications.

WRITTEN DESCRIPTION

A patent must contain a written description of the product or method claimed in the patent. To satisfy the written description requirement, the patent must describe each and every limitation of a patent claim, although the exact words found in the claim need not be used.

The written description requirement does not require the applicant to describe exactly the subject matter claimed. Nor does it require that a patent specification set forth in a single embodiment all the steps of a claimed invention. Compliance with the written description requirement requires that the specification of a patent, when considered as a whole, reasonably describes the inventions claimed in that patent.

Smith & Nephew contends that claims 46, 47 and 56 of the '536 patent are invalid for lack of an adequate written description of the claimed invention. If you find that Smith & Nephew has proven by clear and convincing evidence that these patents do not contain a written description of the invention covered by a claim, then you must find that claim invalid.

INDEFINITENESS

Smith & Nephew contends that certain claims of the '536, '882 and '592 patents are invalid for indefiniteness. The patent laws require the claims of a patent to be sufficiently definite so that one skilled in the art can determine the scope of the claimed invention. To establish indefiniteness, Smith & Nephew must prove by clear and convincing evidence that the claims, when read in light of the specification, do not reasonably apprise those skilled in the art of the scope of the invention.

The amount of detail required to be included depends on the particular invention and the prior art, and is not evaluated in the abstract but in conjunction with the disclosures. If the claims, read in light of the disclosures, reasonably apprise those skilled in the art of the proper scope of the invention, then the claims are not indefinite.

Simply because some claim language may not be precise does not automatically render a claim invalid. Patentable inventions cannot always be described in terms of exact measurements, symbols or formulas. For instance, patentees can use terms such as ~~substantially~~ or ~~about~~ when defining their invention. Claims do not have to be plain on their face or be as precise or specific as they might possibly be drafted, so long as the meaning of the claim is discernible. Compliance with the definiteness requirement depends on what one skilled in the art would determine to be the bounds of the claims in light of the specification. Even if one skilled in the art needed to

experiment so as to determine the limits of the claims of the patents, that would not necessarily be a basis for holding the claims invalid.

If you find that Smith & Nephew has proven by clear and convincing evidence that claim 47 of the '536 patent and the asserted claims of the '592 are not definite enough that a skilled person reading them knows what is covered by the claims, and what is not, then you must find these claims invalid.

REEXAMINATION

One of the patents-in-suit, the 536 patent, has been the subject of a reexamination proceeding. Reexamination is a procedure that allows the Patent Office to address substantial new questions of patentability after the issuance of a patent.

Any person may request the reexamination of a patent at any time during the period of enforceability of an issued U.S. patent. The reexamination request must include one or more prior art patents or printed publications, as well as a statement by the requestor outlining the relevance of each cited reference. Upon receipt of the reexamination request, the Patent Office assigns an examiner to the reexamination request.

If the Patent Office grants the reexamination request, the patent examiner may decide to allow, reject or amend patent claims that are the subject of a reexamination. A notice is issued at the end of the proceeding to inform the patent owner and any third party requestor that the prosecution on the merits of the reexamination proceeding is closed. If the patentability of the claims is confirmed, the Patent Office will issue a Notice of Intent to Issue an Ex Parte Reexamination Certificate. A reexamination certificate is then mailed by the Patent Office.

Like any other patent, a patent that has undergone reexamination can be found invalid by a jury.

CERTIFICATE OF CORRECTION

ArthroCare alleges that the '882 patent issued from the Patent Office containing errors. Requesting a certificate of correction is one way to correct certain kinds of errors in patents. Once properly corrected by a certificate of correction, a patent shall have the same effect and operation in law as if it were originally issued in the corrected form. ArthroCare requested and obtained a certificate of correction for its patent. Smith & Nephew challenges the validity of that certificate of correction and has the burden of proving invalidity by clear and convincing evidence.

When the patent applicant is the one who - like ArthroCare - made the error, it can use a certificate of correction only to correct errors of a clerical or typographical nature. An error is clerical or typographical if one of skill in the art can tell just from looking at the patent and the prosecution history that there was an error, and also how that error should be corrected. A certificate of correction for any other errors is not valid and can be challenged in court.

DELIBERATION AND VERDICT

DUTY TO DELIBERATE

Now that all of the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong.

But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that -- your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

If any member of the jury took notes, let me remind you that notes are not entitled to any greater weight than the memory or impression of each juror as to what the testimony may have been. Whether you took notes or not, each of you must form and express your own opinion as to the facts of the case.

If you did not take notes, you should rely upon your own memory of what was said and not be overly influenced by the notes of other jurors.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

JURY QUESTIONS

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I will have to talk to the lawyers about what you have asked, so it may take me some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this court is juror no. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

UNANIMOUS VERDICT

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges -- judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A special verdict form has been prepared for you. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form. Each of you will then sign the form. You will then return to the courtroom and your foreperson will submit your verdict to the court.

It is proper to add the caution that nothing said in these instructions and nothing in the form of special verdict is meant

to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is the sole and exclusive duty and responsibility of the jury.

COURT HAS NO OPINION

Let me finish up by saying that nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.

(405)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

JURY VERDICT

We, the jury, unanimously find as follows:

L. INFRINGEMENT OF ARTHROCARE'S PATENTS

A. The '536 Patent

Direct Infringement by Smith & Nephew of the '536 Patent

1. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has directly infringed any of the following claims of the '536 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'536	46	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	47	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	56	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO

Inducement of Infringement by Smith & Nephew

2. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has induced infringement by others of any of the following claims of the '536 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'536	46	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	47	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	56	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO

Contributory Infringement by Smith & Nephew

3. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has contributed to the infringement any of the following claims of the '536 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'536	46	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	47	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	56	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO

B. The '882 Patent

Validity of ArthroCare's Certificate of Correction for the '882 Patent

4. Do you find that Smith & Nephew has shown by clear and convincing evidence that the certificate of correction for claim 1 of the '882 patent is invalid? (A "YES" answer to this question is a finding for Smith & Nephew. A "NO" answer is a finding for ArthroCare.)

Patent	Claim	Invalid
'882	1	YES <input checked="" type="radio"/> NO

Answer questions 5-6 only if you have answered "NO" in question 4.

Inducement of Infringement by Smith & Nephew of the '882 Patent

5. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has induced infringement by others of any of the following claims of the '882 patent with its Saphyre or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	Control RF
'882	13	<input checked="" type="radio"/> YES <input type="radio"/> NO	
'882	17	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'882	54		<input checked="" type="radio"/> YES <input type="radio"/> NO

Contributory Infringement by Smith & Nephew of the '882 Patent

6. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has contributed to the infringement of any of the following claims of the '882 patent with its Saphyre or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	Control RF	Electroshock	Control RF
'882	13	<input checked="" type="radio"/> YES <input type="radio"/> NO			
'882	17	<input checked="" type="radio"/> YES <input type="radio"/> NO			<input checked="" type="radio"/> YES <input type="radio"/> NO
'882	54		<input checked="" type="radio"/> YES <input type="radio"/> NO		<input checked="" type="radio"/> YES <input type="radio"/> NO

C. The '592 Patent

Inducement of Infringement by Smith & Nephew of the '592 Patent

7. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has induced infringement by others of any of the following claims of the '592 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'592	1	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	3	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	4	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	11	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	21			<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	23	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	26	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	27	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	32	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	42			<input checked="" type="radio"/> YES <input type="radio"/> NO

Contributory Infringement by Smith & Nephew of the '592 Patent

8. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has contributed to the infringement of any of the following claims of the '592 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'592	1	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	3	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	4	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	11	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	21			<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	23	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	26	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	27	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	32	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	42			<input checked="" type="radio"/> YES <input type="radio"/> NO

II. VALIDITY OF ARTHROCARE'S PATENTS

A. Anticipation of ArthroCare's Patents

9. Do you find that Smith & Nephew has shown by clear and convincing evidence that the following claims of the patents-in-suit are invalid due to anticipation? (A "YES" answer to this question is a finding for Smith & Nephew. A "NO" answer is a finding for ArthroCare.)

The '536 Patent

	Anticipated	
Claim 46	YES	<input checked="" type="radio"/> NO
Claim 47	YES	<input checked="" type="radio"/> NO
Claim 56	YES	<input checked="" type="radio"/> NO

The '882 Patent

	Anticipated	
Claim 13	YES	<input checked="" type="radio"/> NO
Claim 17	YES	<input checked="" type="radio"/> NO
Claim 54	YES	<input checked="" type="radio"/> NO

The '592 Patent

	Anticipated	
Claim 1	YES	<input checked="" type="radio"/> NO
Claim 3	YES	<input checked="" type="radio"/> NO
Claim 4	YES	<input checked="" type="radio"/> NO
Claim 11	YES	<input checked="" type="radio"/> NO
Claim 21	YES	<input checked="" type="radio"/> NO
Claim 23	YES	<input checked="" type="radio"/> NO
Claim 26	YES	<input checked="" type="radio"/> NO
Claim 27	YES	<input checked="" type="radio"/> NO
Claim 32	YES	<input checked="" type="radio"/> NO
Claim 42	YES	<input checked="" type="radio"/> NO

D. Enablement of ArthroCare's Patent

10. Do you find that Smith & Nephew has shown by clear and convincing evidence that the following claims are invalid for lack of enablement? (A "YES" answer to this question is a finding for Smith & Nephew. A "NO" answer is a finding for ArthroCare.)

Patent	Claims	Invalid
'882	13, 17, 54	YES <input checked="" type="radio"/> NO

Each Juror should sign the verdict form to reflect that a unanimous verdict has been reached.

Dated: May 12, 2003

Delphine Adkins
Foreperson

Stacy Miranda

Christine M. Murray

Sharon Hansen

Bernice H. O'Neil

Jeff L. Byrnes

Carol Hansen

John X. O'Neil



US005697536A

United States Patent [19]

Eggers et al.

[11] Patent Number: 5,697,536

[45] Date of Patent: Dec. 16, 1997

[54] SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION[75] Inventors: Phillip E. Eggers, Dublin, Ohio; Hira
V. Thapliyal, Los Altos, Calif.[73] Assignee: Arthrocare Corporation, Sunnyvale,
Calif.

[21] Appl. No.: 746,840

[22] Filed: Nov. 18, 1996

Related U.S. Application Data

[60] Division of Ser. No. 485,219, Jan. 7, 1995, which is a
continuation-in-part of Ser. No. 446,767, Jan. 2, 1993,
which is a continuation-in-part of Ser. No. 39,541, May 10,
1993, abandoned, which is a continuation-in-part of Ser. No.
958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a
continuation-in-part of Ser. No. 817,573, Jan. 7, 1992,
abandoned.[31] Int. Cl.⁴ _____ A61M 37/00

[52] U.S. Cl. _____ 604/114; 604/22

[58] Field of Search _____ 604/22, 43, 48,
604/113, 114, 264, 271, 280; 606/31, 28,
29, 39, 41, 45

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4,326,529	4/1982	Doss	_____	128/303.1
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4,979,948	12/1990	Geddes et al.	_____	606/33
4,998,933	3/1991	Eggers et al.	_____	606/41

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0 740 926	11/1996	European Pat. Off.	_____	A61B 17/39
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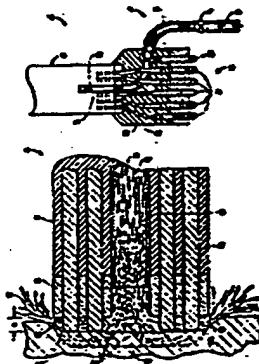
Primary Examiner—Manuel Mendez

Attorney, Agent, or Firm—Townsend and Townsend and
Crew LLP

[57] ABSTRACT

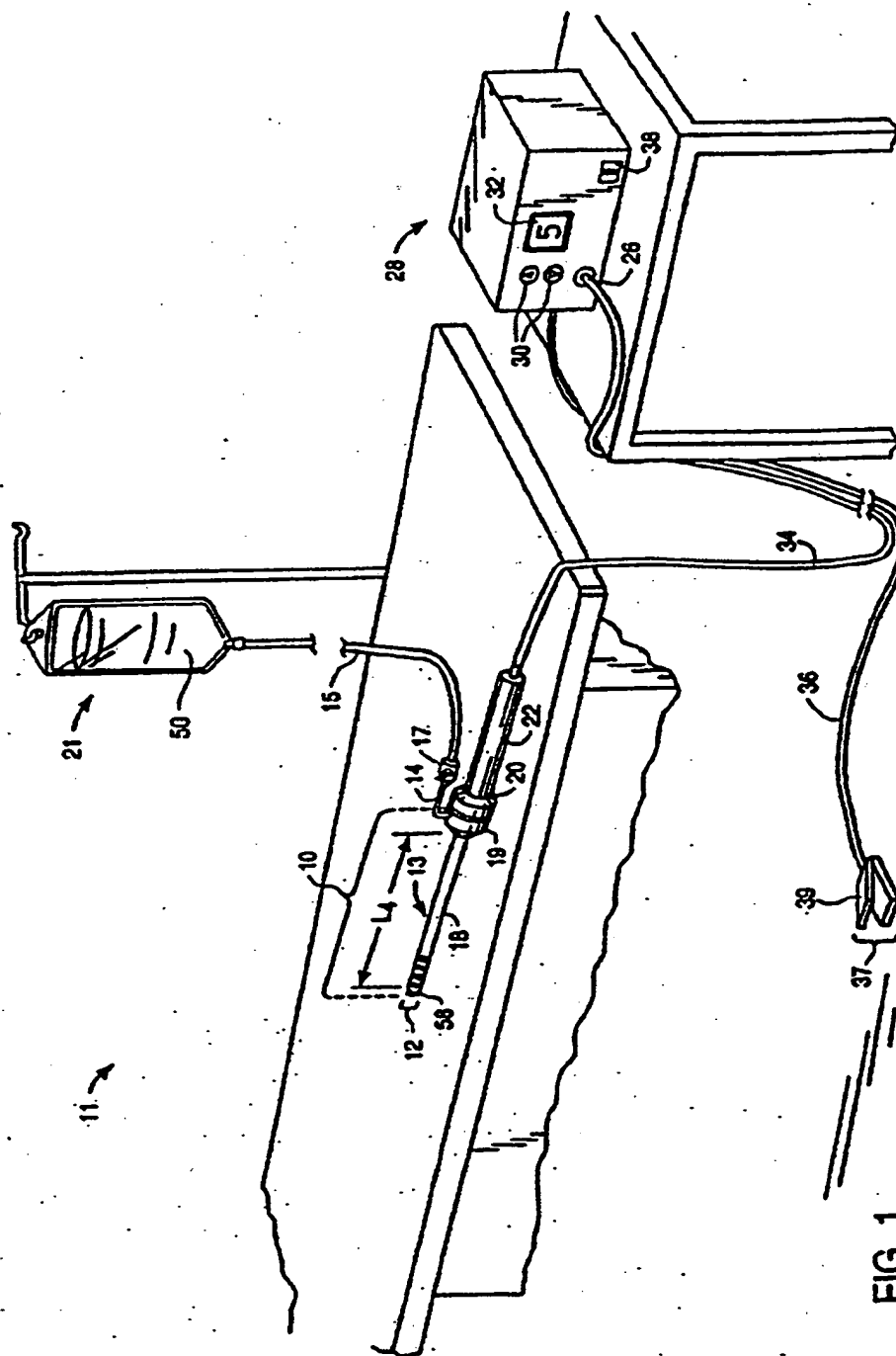
An electrosurgical probe (10) comprises a shaft (13) having an electrode array (12) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (35, 36) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (56). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the target site and the return electrode so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the return electrode and the target site.

64 Claims, 10 Drawing Sheets



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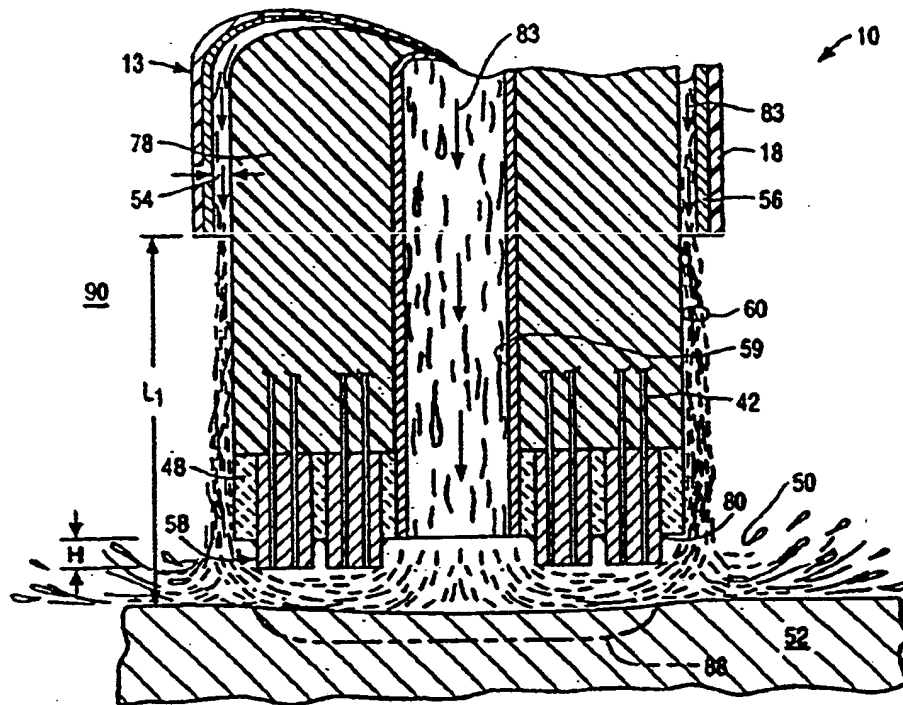


FIG. 2A

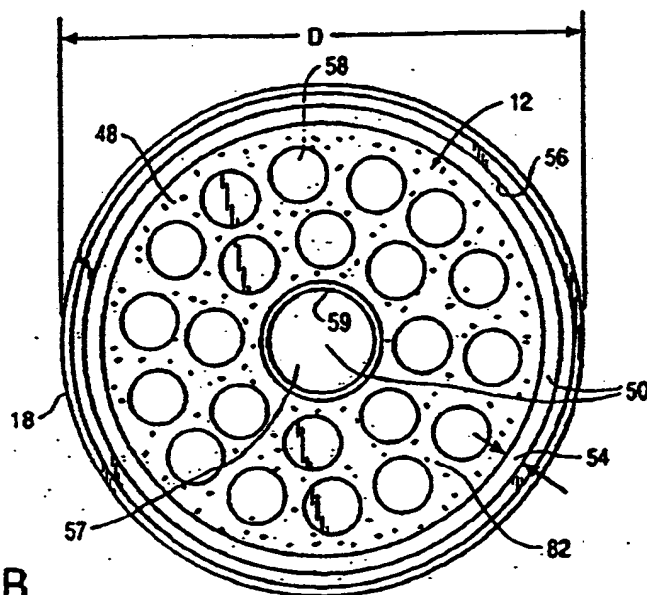
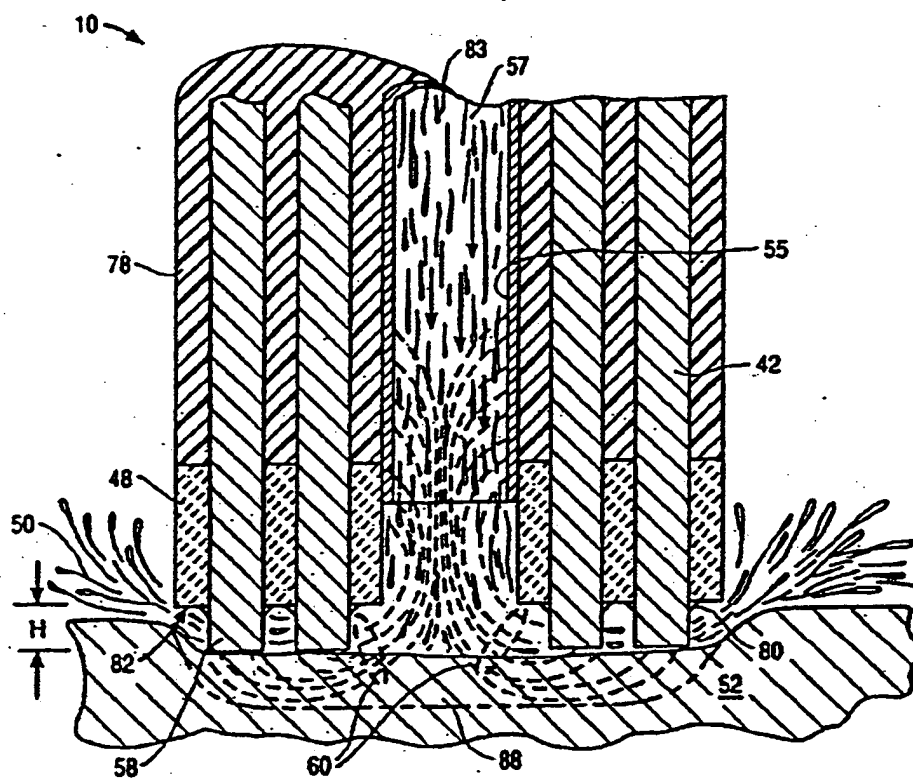
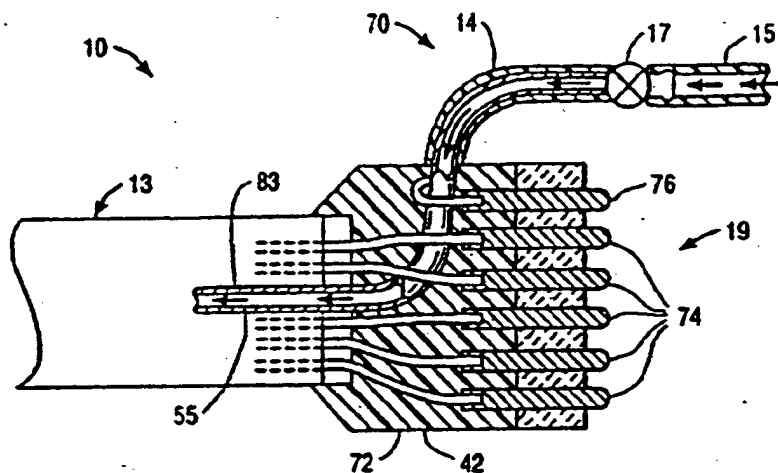


FIG. 2B



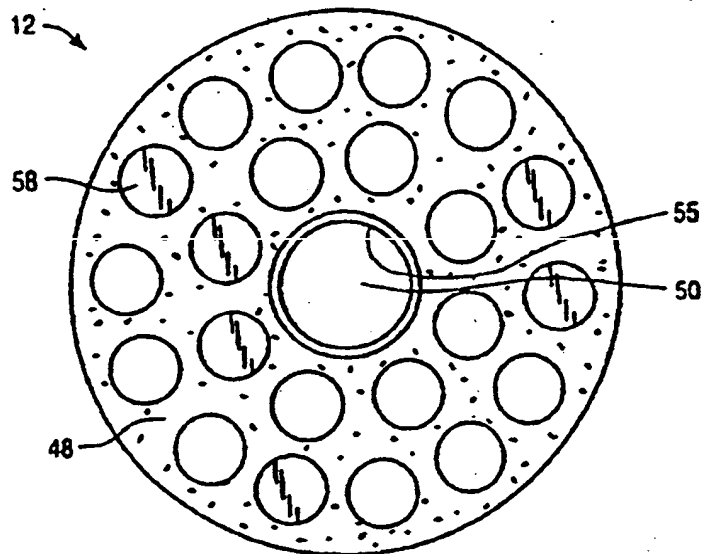


FIG. 4

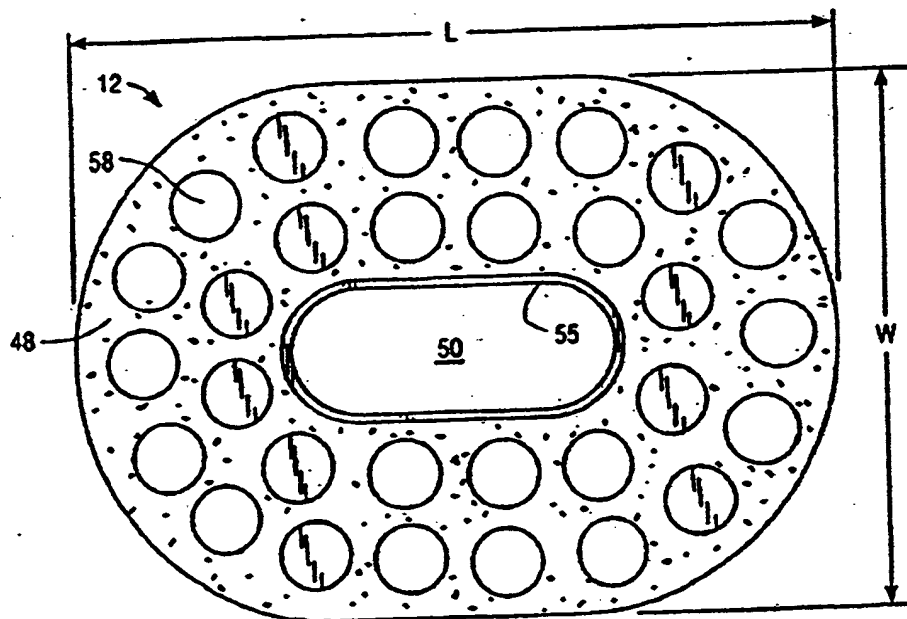


FIG. 5

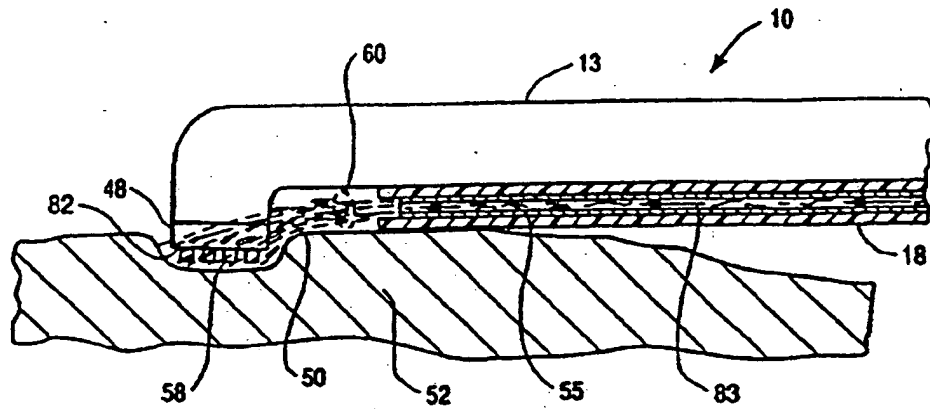


FIG. 6

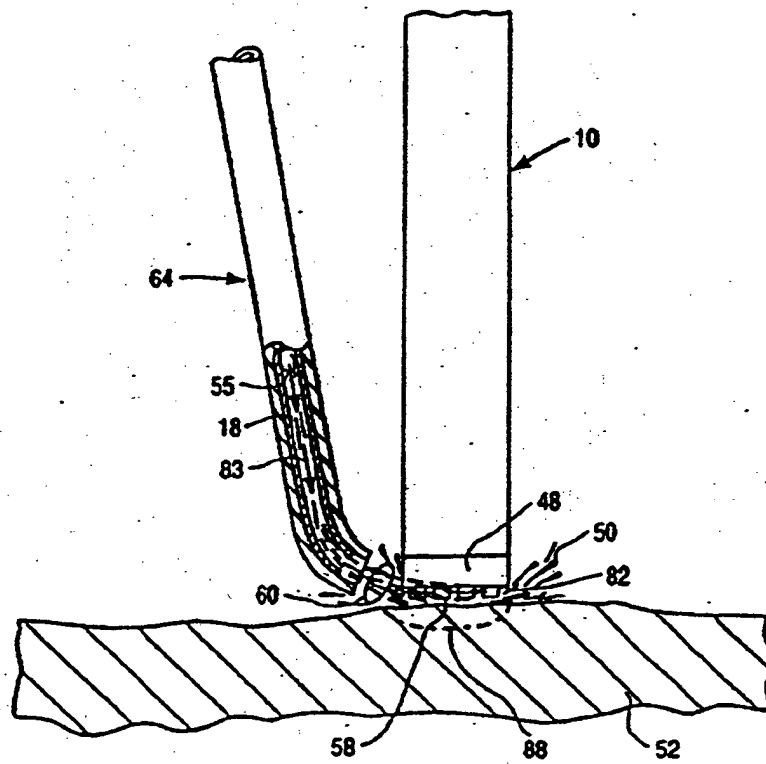


FIG. 7

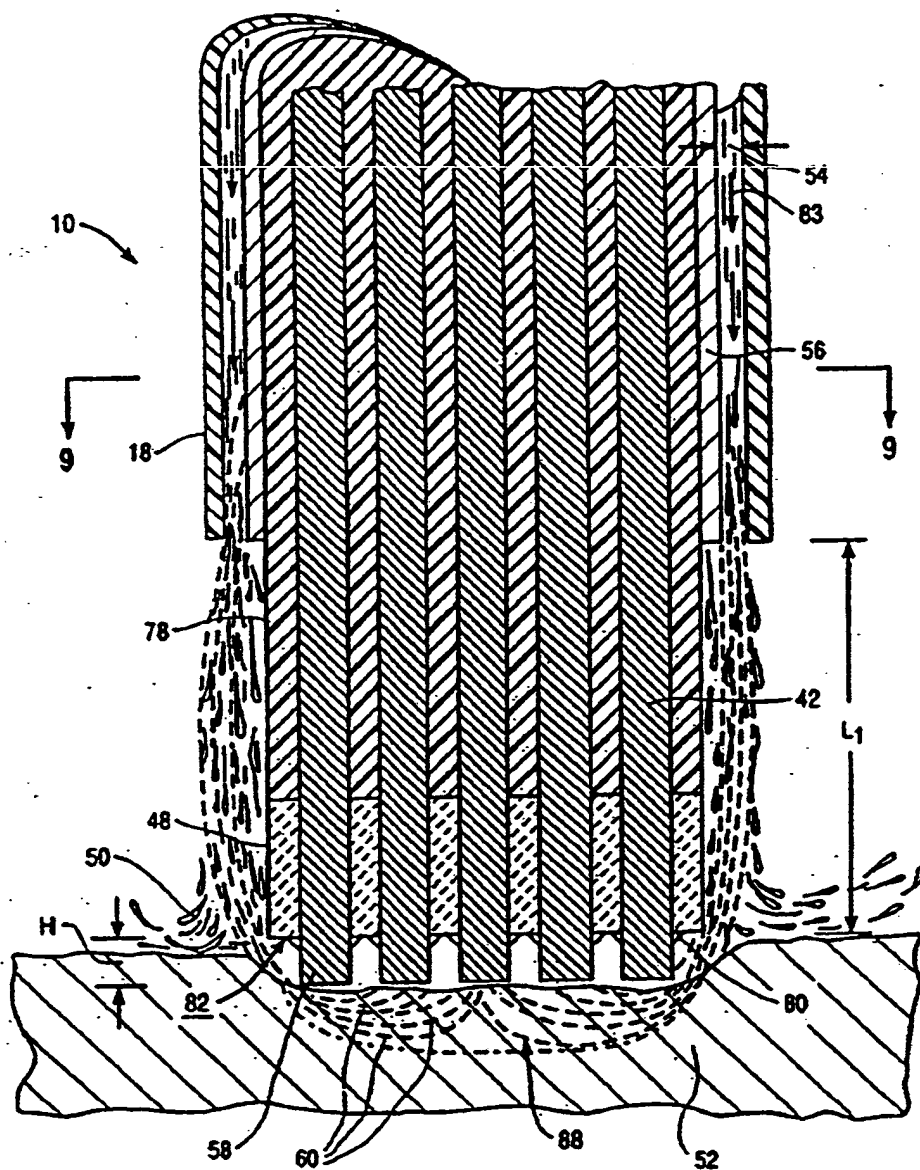


FIG. 8

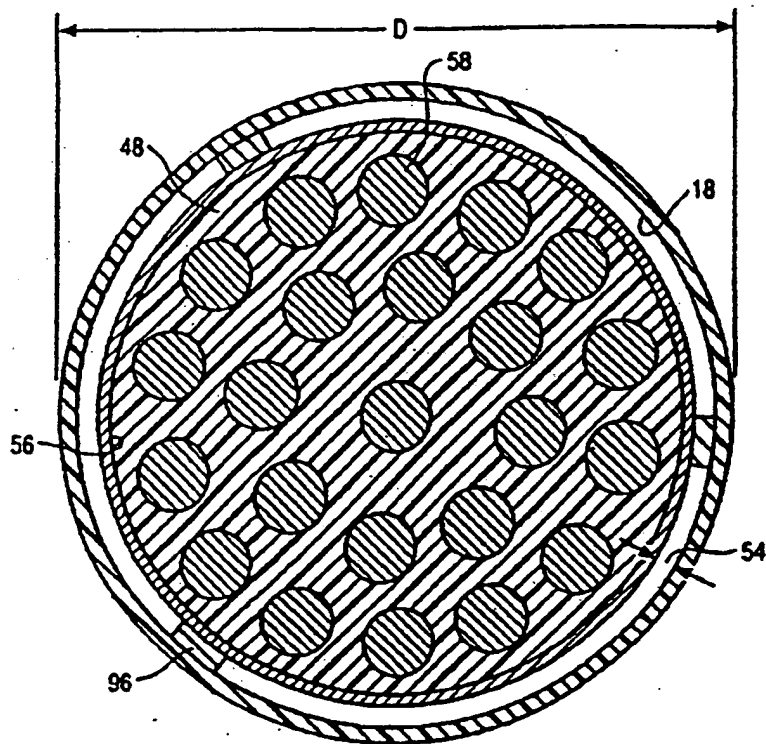


FIG. 9

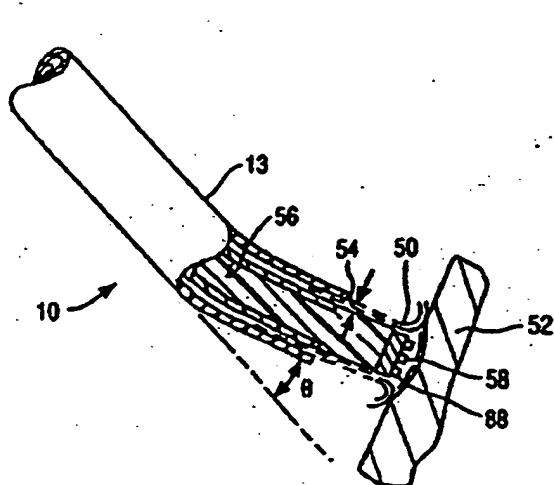


FIG. 10

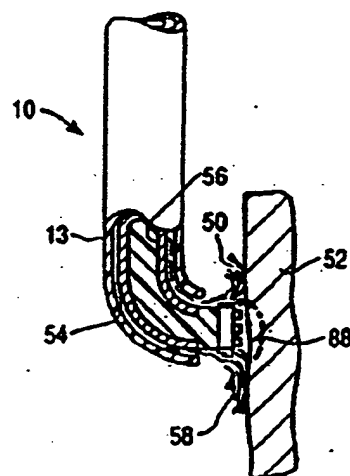


FIG. 11

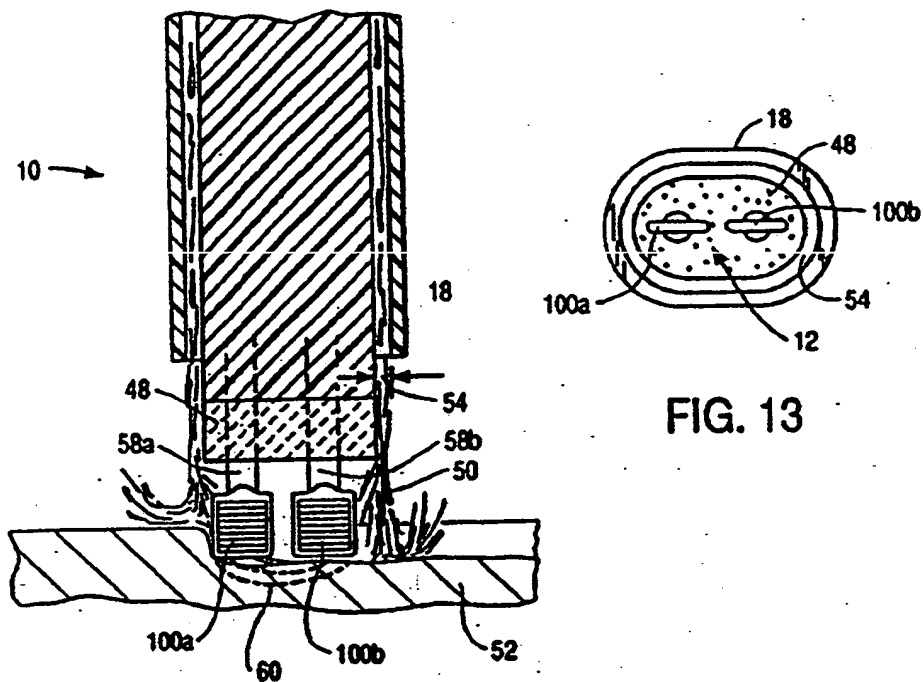


FIG. 12

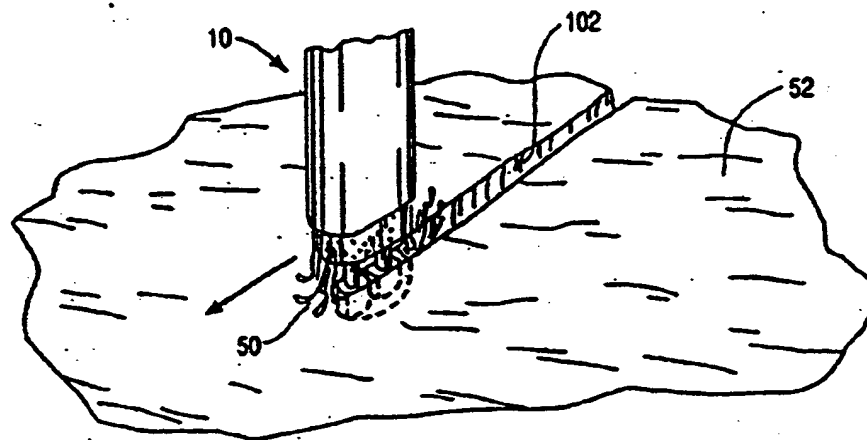


FIG. 14

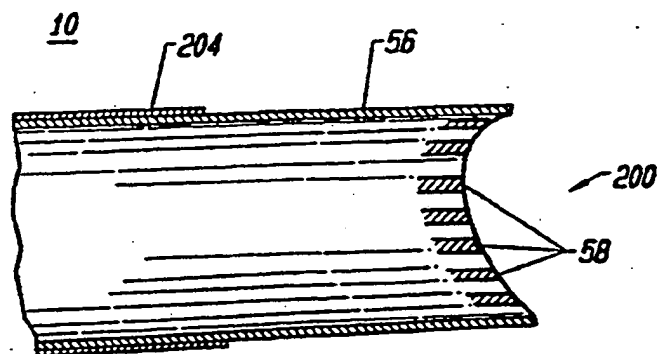


FIG. 15

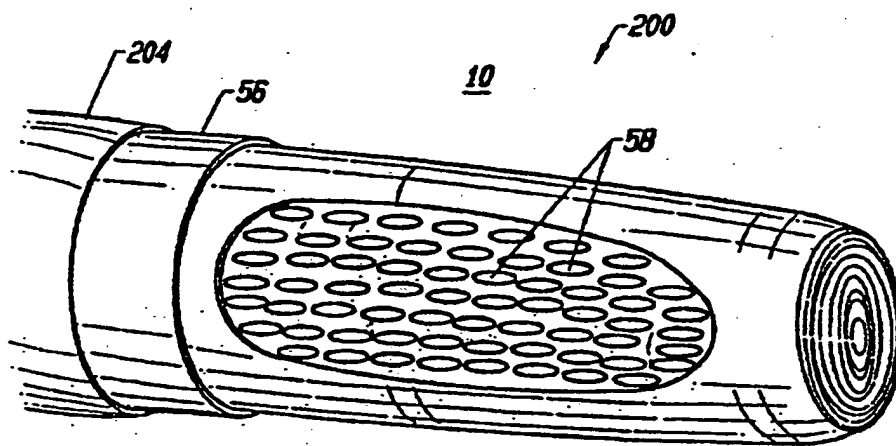
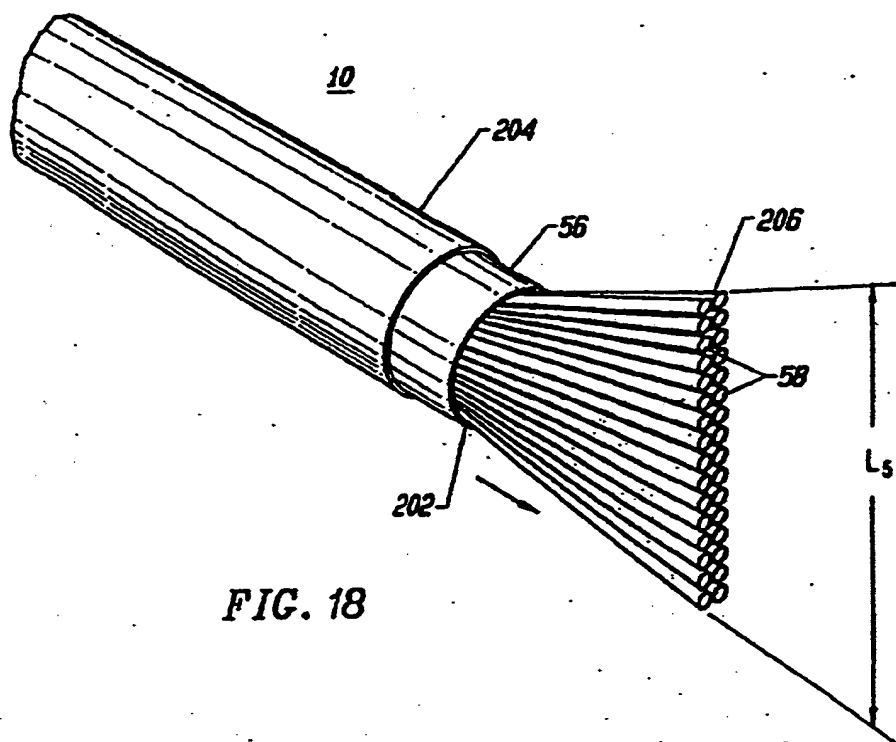
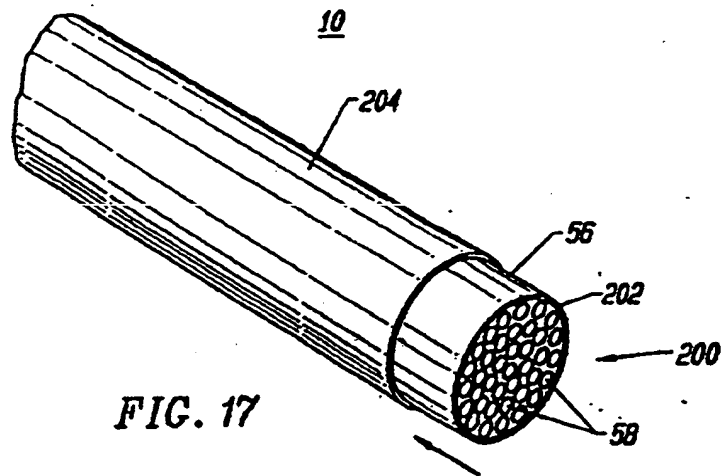


FIG. 16



SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

This is a Division of application Ser. No. 08/485,219 filed Jun. 7, 1995 pending, which is a continuation-in-part of application Ser. No. 08/446,767 filed on Jun. 2, 1995 and pending; which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993, now abandoned; which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992, now U.S. Pat. No. 5,366,443; which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992, now abandoned; the full disclosures of which are incorporated herein by reference.

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Additionally, electrosurgical ablation procedures, where tissue surfaces and volume may be reshaped, cannot be duplicated through other treatment modalities.

Current electrosurgical devices and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying surrounding tissue.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may

cause tissue desiccation or destruction at its contact point with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

In response to the various problems associated with electrosurgical procedures in electrically conductive environments, new methods and devices have been developed by the applicant. These methods and devices provide selective power delivery to the target tissue while minimizing power delivery to the surrounding electrically conductive irrigant. These methods are particularly useful in isotonic saline filled body cavities, such as arthroscopic, urologic or gynecologic cavities. The irrigant flooded body cavity provides good visibility, facilitates the removal of bubbles or other debris, minimizes the possibility of air embolism and protects certain tissue from dehydration. Such methods and devices are more fully described in previously filed, commonly assigned applications Ser. Nos. 08/059,681, 07/958,977 and 07/817,575, the full disclosures of which have been incorporated by reference.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth or the ablation and necrosis of diseased tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of tissue. These systems and methods should be capable of providing a direct return current path from the active electrode, through the target site, to the return electrode to minimize the dangers of electrical current flowing through undefined paths in the patient's body. The system should also be configured to minimize contact between the return electrode and surrounding tissue and to avoid current shorting between the active and return electrodes. Preferably, the system will be configured to apply high frequency voltage for the cutting and ablation of tissue in relatively dry environments, such as those encountered in oral, laparoscopic and open surgical procedures.

2. Description of the Background Art

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1: 242-246

and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

SUMMARY OF THE INVENTION

The present invention provides an apparatus and method for selectively applying electrical energy to structures within a patient's body. The apparatus and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, without requiring the tissue to be submerged in an electrically conducting irrigant, such as isotonic saline. The apparatus and method of the present invention are particularly useful for treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, and ablation and necrosis of diseased tissue, such as tumors.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into at least partial contact or close proximity with the target site. Electrically conducting liquid, such as isotonic saline, is directed through a fluid path past a return electrode and to the target site to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The above described method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, laparoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In laparoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and to shield the return electrode from tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner passage

for flow of electrically conducting liquid therethrough. The liquid is directed through the return electrode and over the active electrode to thereby provide a return current flow path between the tissue target site and the return electrode.

In a preferred aspect of the invention, the active electrode comprises an electrode array having a plurality of electrically isolated electrode terminals disposed over a contact surface, which may be a planar or non-planar surface and which may be located at the distal tip or over a lateral surface of the shaft, or over both the tip and lateral surface(s). The electrode array will include at least two and preferably more electrode terminals, and may further comprise a temperature sensor. In a preferred aspect, each electrode terminal will be connected to the proximal connector by an electrically isolated conductor disposed within the shaft. The conductors permit independent electrical coupling of the electrode terminals to a high frequency power supply and control system with optional temperature monitor for operation of the probe. The control system preferably incorporates active and/or passive current limiting structures, which are designed to limit current flow when the associated electrode terminal is in contact with a low resistance return path back to the return electrode.

The use of such electrode arrays in electrosurgical procedures is particularly advantageous as it has been found to limit the depth of tissue necrosis without substantially reducing power delivery and ablation rates. The voltage applied to each electrode terminal causes electrical energy to be imparted to any body structure which is contacted by, or comes into close proximity with, the electrode terminal, where a current flow through all low electrical impedance paths is preferably but not necessarily limited. It will be appreciated that such low impedance paths generally occur when an electrode terminal does not contact or come into close proximity with the body structure, but rather is in contact with a low impedance environment, such as the saline, or other electrolyte being introduced past the return electrode. The presence of an electrolyte provides a relatively low impedance path back to the common or return electrode.

The apparatus and method of the present invention provide a number of advantages, particularly in respect to the ablation or cutting of tissue. The ability to control current flow through individual electrode terminals minimizes power dissipation into the surrounding medium. Limited power dissipation, in turn, permits the use of electrolytic irrigants, such as isotonic saline, to create a current flow path between the active electrode terminals and the return electrode. The isotonic saline may also be used to simultaneously irrigate the surgical site, which provides a number of well known physiological advantages. In addition, the ability to operate in a bipolar or quasi-bipolar mode reduces the risk of unwanted electrical stimulation from return current flowing through the patient's body, which can cause muscle spasms and can limit the depth of tissue necrosis during ablative resection.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12; and

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue.

FIG. 15 illustrates another alternative electrode surface configuration for the electrosurgical probe of FIG. 1.

FIG. 16 illustrates a second alternative electrode surface configuration.

FIGS. 17 and 18 illustrate an electrosurgical probe having an electrode surface which can be transformed from a flat, circular array (FIG. 17) to an elongate, linear array (FIG. 18) suitable for use in surgical cutting.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an apparatus and method for selectively applying electrical energy to a target location within a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

The present invention uses an electrode array including a plurality of independently current-limited and/or power-

controlled electrode terminals distributed over a distal contact surface of a probe to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an electrode array near its distal end. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the electrode array and permit the treating physician to manipulate the array from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently is in the range from 1 to 10 mm. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) against or in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in contact or close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

Each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g.,

blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof.

The tip region of the probe is thus composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to of the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the said common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor or other connective tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm²,

and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

The rate of energy delivery to the target tissue is controlled by the applied voltage level and duty cycle of the voltage pulse. The use of high frequency current minimizes induced stimulation of muscle tissue or nerve tissue in the vicinity of the body structure being treated. In addition, high frequencies minimize the risk of interfering with the natural pacing of the heart in circumstances where the probe of the present invention is used near the heart.

The power applied to the common electrode and the electrode array will be at high or radio frequency, typically between about 20 kHz and 20 MHz, usually being between about 30 kHz and 2 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 10 volts to 300 volts. Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired surface temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate

average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, open surgery or other endoscopic surgery procedure.

The power source will be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 20 μ H to 5000 μ H, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, which has already been incorporated herein by reference. Additionally, current limiting resistors may be selected having a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode from being energized during given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this

example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

The electrode array is formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and array of active electrodes. In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of laparoscopic or endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Electrode array contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, or virtually any other regular or irregular shape. Most commonly, the electrode arrays will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the electrode arrays may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 54 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT/US94/05168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 1 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.5 mm to 7 mm, as shown in FIG. 3. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3). As described above, electrode terminals which are flush with the surface, or protrude by a minimum distance, will provide less aggressive ablation and are particularly suitable for smoothing of treated tissue surfaces and providing hemostasis to inhibit or prevent bleeding of treated surfaces.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, platinum alloys, titanium, titanium alloys and the like. Platinum is the preferred choice for electrode terminal material since it is biocompatible, has a low erosion rate, and can be readily fabricated and attached to conductors 42 within the shaft 13 of electrosurgical probe 10. As shown in FIG. 2B, the electrode terminals 58 are anchored in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes are then bonded to the distal surface 82 of support matrix 48, typically by an isorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the alumina matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.25 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 1 mm to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyamide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this current path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. Liquid paths 83 are formed by annular gap 54 between outer return electrode 56 and tubular support member 78 and an inner lumen 57 within an inner tubular member 59. The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode. The high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 53 positioned within tubular member 78. Return electrode 53 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 53. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 53 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 53 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 53. Preferably, an insulating jacket 14 covers the exposed portions of electrode 53. One of the connector pins

76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 54.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 54 flows along flow path 83 through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 54 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 54. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 54 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.25 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm.

As shown in FIG. 8, electrically conducting liquid 54 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 54 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shunting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screw-driver shape. The screwdriver shape provides a greater

amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgical team then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

Yet another configuration for tip 200 of probe 10 is shown in FIG. 15 wherein a concave or wedge-shaped arrangement of electrodes 58 is provided to facilitate good contact with target tissue which can be embraced by said concave or wedge-shaped opening. As before, the return electrode 56 may be positioned proximal to probe tip 200.

Still yet another configuration for tip 200 of probe 10 is shown in FIG. 16 wherein electrodes 58 terminate on the side of the generally tubular (e.g., cylindrical) surface proximal to the distal end of probe 10. This configuration allows the electrode array to be brought into contact with target tissue surfaces which are tangent to the tubular surface of probe 10. As before, return electrode 56 may be positioned proximal to probe tip 200.

Another configuration for tip 200 of probe 10 is shown in FIGS. 17 and 18 and features a variable tip configuration which can be adjusted during the course of use of said probe 10. By way of example, tip 200 of probe 10 can be a cylindrical array of electrodes 58 which conforms to the cylindrical geometry of a rigid support member or cannula 202. The distal end of said cannula 202 may also serve as the common electrode 56 which is insulated in regions proximal to the tip region by an electrically insulating member 204. Referring now to FIG. 18, by extending the flexible array of electrodes 58 beyond the orifice of the cannula 202, an alternative electrode configuration can be obtained. By way of example, by placing a flat yet flexible member 206 between electrodes 58 as shown in FIG. 18, the electrode array can assume a flat "blade" shape configuration made up of a multiplicity of individual electrodes 58, each electrically insulated from all other electrodes. Such a configuration change may be advantageous if, after the insertion of the probe through a circular introduction port, the user can change the shape of the electrode array to achieve a flat "blade" shaped array whose width L_2 may be substantially greater than the circular electrode array configuration shown in FIG. 17. The increased width L_2 of the electrode array in FIG. 18 will provide the means for faster cutting through the target tissue since cutting depends primarily on the major dimension of the electrode array, either the diameter of the array (as shown in FIG. 17) or the width, L_2 , of the array (as shown in FIG. 18). If the array width in FIG. 18 is three times as great as the array diameter in FIG. 17, then the rate of cutting of the target tissue can be increased by

approximately a factor of three. An additional benefit is that the depth of necrosis in tissue on either side of the cut made with the flat electrode configuration will be less than with the larger array used in a circular configuration.

What is claimed is:

1. An electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply, the system comprising:

a) an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft for electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode adapted to be electrically coupled to the electrosurgical power supply; and

a fluid delivery element defining a fluid path in electrical contact with the return electrode and the electrode terminal, the fluid path having an inlet adapted to be fluidly coupled to the electrically conducting fluid supply for directing fluid along the fluid path to generate a current flow path between the return electrode and the electrode terminal.

2. An electrosurgical system as in claim 1, wherein the return forms a portion of the shaft of the electrosurgical probe.

3. An electrosurgical system as in claim 2 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and a body structure at the target site when the electrode terminal is positioned in close proximity or in partial contact with the body structure.

4. An electrosurgical system as in claim 2, wherein the return electrode is an inner tubular member and the fluid delivery element comprises an axial lumen within the return electrode, the axial lumen forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

5. An electrosurgical system as in claim 2, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member, wherein the fluid delivery element comprises an axial passage between the insulating member and the return electrode, the axial passage forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

6. An electrosurgical system as in claim 1 wherein the fluid delivery element comprises a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

7. An electrosurgical system as in claim 6 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

8. An electrosurgical system as in claim 7 wherein the fluid supply instrument comprises an electrically insulating sheath around the tubular member, the tubular member being proximally recessed from a distal end of the sheath.

9. An electrosurgical system as in claim 1 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality of electrically isolated electrode terminals disposed over a contact surface.

10. The electrosurgical system of claim 9 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independently controlling current flow to each of the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

11. The electrosurgical system of claim 9 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

12. The electrosurgical system of claim 9 wherein the distal surface of the array of electrode terminals is circular in shape with a diameter in the range from 1 mm to 10 mm.

13. The electrosurgical system of claim 9 wherein the shape of the distal surface of the array of electrode terminals has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

14. The electrosurgical system of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

15. The electrosurgical system of claim 1 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

16. The electrosurgical system of claim 1 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

17. The electrosurgical system of claim 16 wherein the electrically conducting fluid between the electrode terminal and the return electrode has an inherent capacitance, wherein the inherent capacitance of the tissue and electrically conducting fluid between the electrode terminal and the return electrode combined with the current limiting element together form a series resonant output circuit.

18. The system of claim 17 wherein the series resonant circuit has a resonant frequency that varies with changes in the inherent capacitance between the electrode terminal and the return electrode.

19. The electrosurgical system of claim 16 wherein the current limiting element is an active current limiting element for actively limiting current to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

20. The electrosurgical system of claim 19 wherein the active current limiting element measures current flow for a given applied voltage.

21. The electrosurgical system of claim 19 wherein the active current limiting element comprises an impedance sensor for indicating an electrical impedance less than a threshold level.

22. The electrosurgical system of claim 16 wherein the current limiting element is a passive current limiting element selected from the group consisting essentially of inductors, capacitors, resistors and combinations thereof.

23. The electrosurgical system of claim 1 wherein the height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0 to 2 mm.

24. The electrosurgical system of claim 1 wherein the distance between the most distal portion of the return electrode and the most proximal portion of the electrode terminal is in the range from 0.5 to 10 mm.

25. The electrosurgical system of claim 1 wherein the distal surface of the electrode terminal has a shape selected

from the group consisting essentially of flat, concave, convex, hemispherical, linear (in-line), pyramidal, conical and cylindrical.

24. The electrosurgical system of claim 1 wherein the fluid delivery element further comprises a control valve positioned on the shaft of the probe for controlling flow of the electrically conducting fluid through the fluid path.

27. The electrosurgical system of claim 1 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

28. The electrosurgical system of claim 1 further comprising an insulating matrix surrounding and supporting the electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

29. The electrosurgical system of claim 28 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

34. The electrosurgical system of claim 1 wherein the electrode terminal and the return electrode are configured to effect the electrical breakdowns of tissue in the immediate vicinity of the electrode terminal when high frequency voltage is applied between the electrode terminal and the return electrode in the presence of electrically conducting fluid.

31. The electrosurgical system of claim 1 wherein the electrically conducting fluid is selected from the group consisting essentially of blood and electrolytic irrigants.

32. The electrosurgical system of claim 1 wherein the electrically conducting fluid comprises saline.

33. The electrosurgical system of claim 1 wherein the electrode terminal has a distal portion configured for generating high electric field intensities sufficient to cause molecular disintegration of a body structure at the target site.

34. The electrosurgical system of claim 1 further comprising a temperature sensor adjacent the electrode terminal, the temperature sensor being adapted to be electrically coupled to the high frequency voltage source such that power delivery to the electrode terminal is limited if the measured temperature exceeds a threshold value.

35. The electrosurgical system of claim 34 wherein the temperature sensor is integral with the electrode terminal.

36. The electrosurgical system of claim 1 wherein the distal surface of the electrode terminal is circular in shape with a diameter in the range from 1 mm to 10 mm.

37. The electrosurgical system of claim 1 wherein the shape of the distal surface of the electrode terminal has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

38. The system of claim 1 wherein the electrode terminal is configured for the cutting of tissue.

39. The system of claim 1 wherein the probe comprises a concave-shaped portion, the electrode terminal being disposed within the concave-shaped portion such that the concave-shaped portion at least partially surrounds the target site when the electrode terminal is brought into at least partial contact or close proximity with the target site.

40. The system of claim 1 wherein the probe comprises a lateral surface, the electrode terminal being positioned on the lateral surface such that the electrode terminal may be brought into at least partial contact or close proximity with the tissue surfaces which are substantially tangent to the electrosurgical probe.

41. The system of claim 1 wherein the electrode terminal and the return electrode are configured, upon the application

of sufficient voltage therebetween, to effect the ablation of tissue adjacent the electrode terminal such that a portion of said tissue is volumetrically removed.

42. The system of claim 1 wherein the electrode terminal is disposed at the distal tip of the electrosurgical probe.

43. The system of claim 42 wherein the return electrode is disposed proximally of the electrode terminal on the electrosurgical probe.

44. The system of claim 1 wherein the electrode terminal is a flexible electrode terminal disposed at the distal tip of the probe, the flexible electrode terminal being extendable relative to the distal tip of the probe.

45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft, electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply; and

an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.

46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.

47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.

48. An electrosurgical system as in claim 46, wherein the return electrode is an inner tubular member defining an axial lumen within the return electrode, the axial lumen having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

49. An electrosurgical system as in claim 46, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member defining an axial passage between the insulating member and the return electrode, the axial passage having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

50. An electrosurgical system as in claim 45 further including a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

51. An electrosurgical system as in claim 50 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

52. The electrosurgical system of claim 51 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independent controlling current flow through the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

53. An electrosurgical system as in claim 45 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality

of electrically isolated electrode terminals disposed over a contact surface.

54. The electrosurgical system of claim 53 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

55. The electrosurgical system of claim 45 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

57. The electrosurgical system of claim 45 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

58. The electrosurgical system of claim 45 wherein the frequency of the voltage applied between the return electrode and the electrode terminal is in the range of about 20 kHz and 20 MHz.

59. The electrosurgical system of claim 45 wherein the voltage applied between the electrode terminal and the return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS).

60. The electrosurgical system of claim 45 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

61. The electrosurgical system of claim 45 further comprising an insulating matrix surrounding and supporting

electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

62. The electrosurgical system of claim 45 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

63. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply;

an electrically conducting fluid supply;

a fluid delivery element defining a fluid path electrically coupled to the electrode terminal for directing electrically conducting fluid to the target site and the electrode terminal to substantially surround the electrode terminal with electrically conducting fluid and to locate electrically conducting fluid between the electrode terminal and the target site.

64. The system of claim 63 wherein the return electrode is located on a surface of the patient's body.

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US005697536A

United States Patent [19]

Eggers et al.

[11] Patent Number: 5,697,536

[45] Date of Patent: Dec. 16, 1997

[54] SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION[75] Inventors: Philip E. Eggers, Dublin, Ohio; Hira
V. Thapliyal, Los Altos, Calif.[73] Assignee: Arthrocare Corporation, Sunnyvale,
Calif.

[21] Appl. No.: 746,800

[22] Filed: Nov. 18, 1996

Related U.S. Application Data

[60] Division of Ser. No. 485,219, Jun. 7, 1995, which is a
continuation-in-part of Ser. No. 446,767, Jun. 2, 1995,
which is a continuation-in-part of Ser. No. 59,681, May 10,
1993, abandoned, which is a continuation-in-part of Ser. No.
958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a
continuation-in-part of Ser. No. 817,575, Jan. 7, 1992,
abandoned.[51] Int. Cl.⁶ _____ A61M 37/00

[52] U.S. Cl. _____ 604/114; 604/22

[58] Field of Search _____ 604/22, 43, 48,
604/113, 114, 264, 271, 280; 606/31, 28,
29, 39, 41, 45

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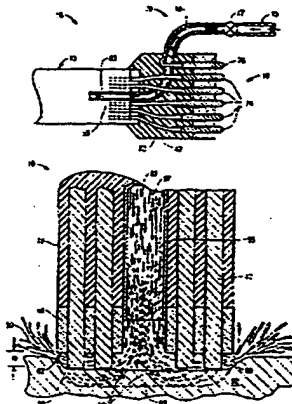
Primary Examiner—Manuel Mendez

Attorney, Agent, or Firm—Townsend and Townsend and
Crew LLP

[57] ABSTRACT

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (12) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (55, 56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the target site and the return electrode so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the return electrode and the target site.

64 Claims, 10 Drawing Sheets



A400.1

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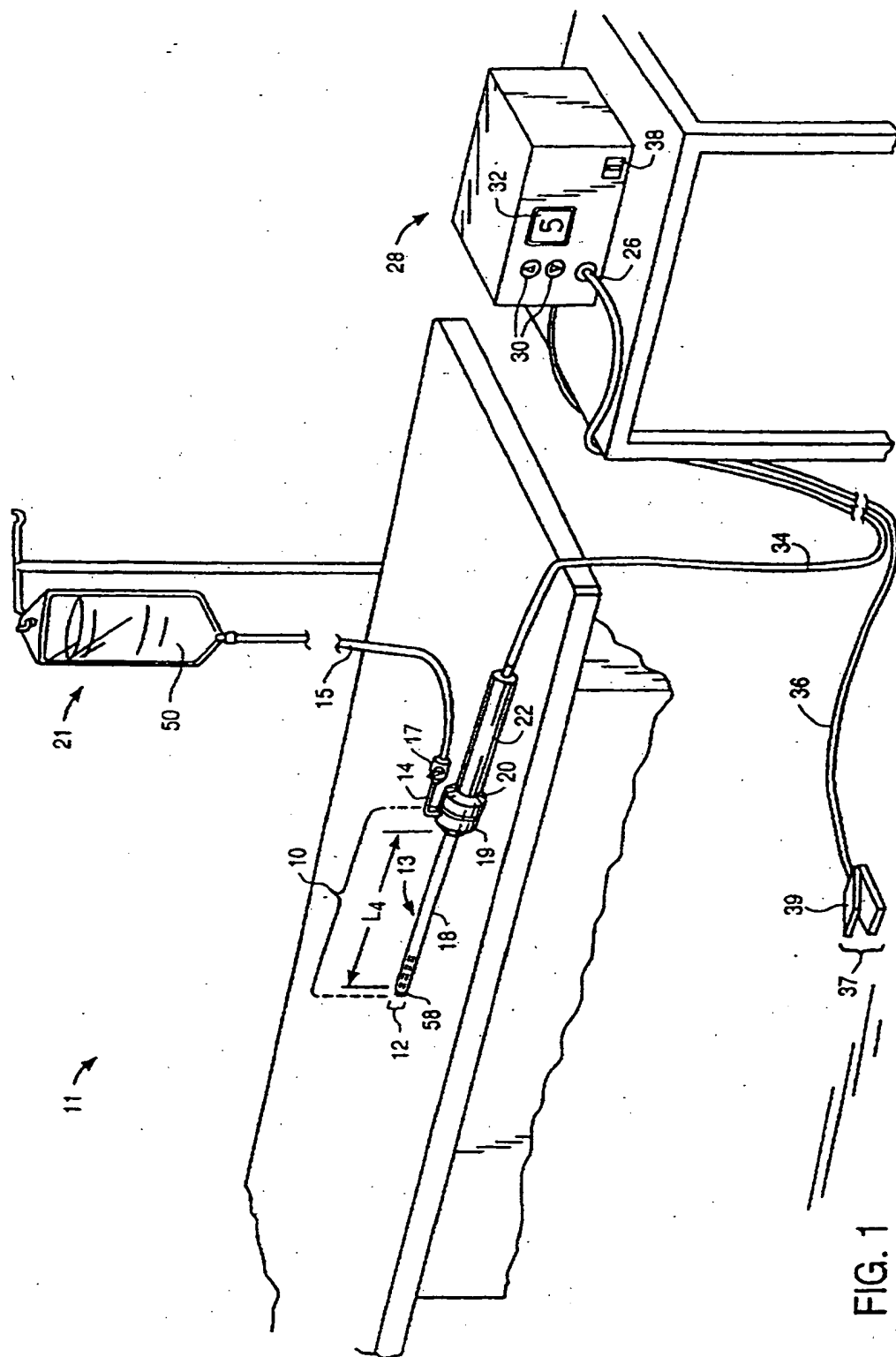


Fig. 1

A400.3

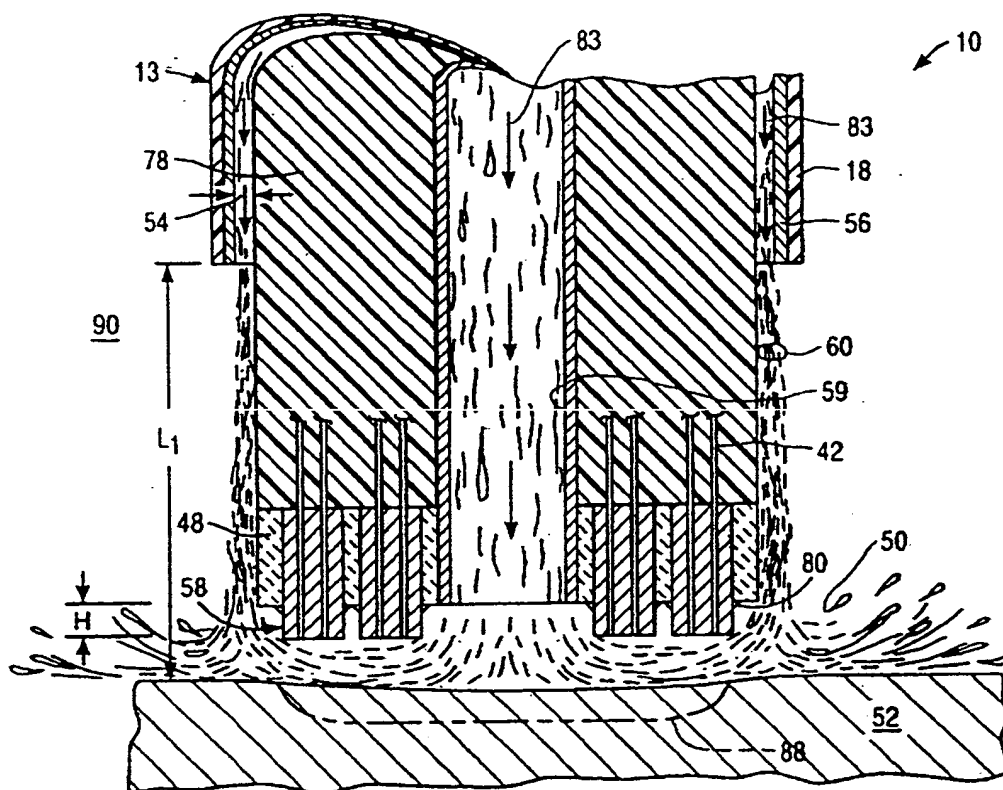


FIG. 2A

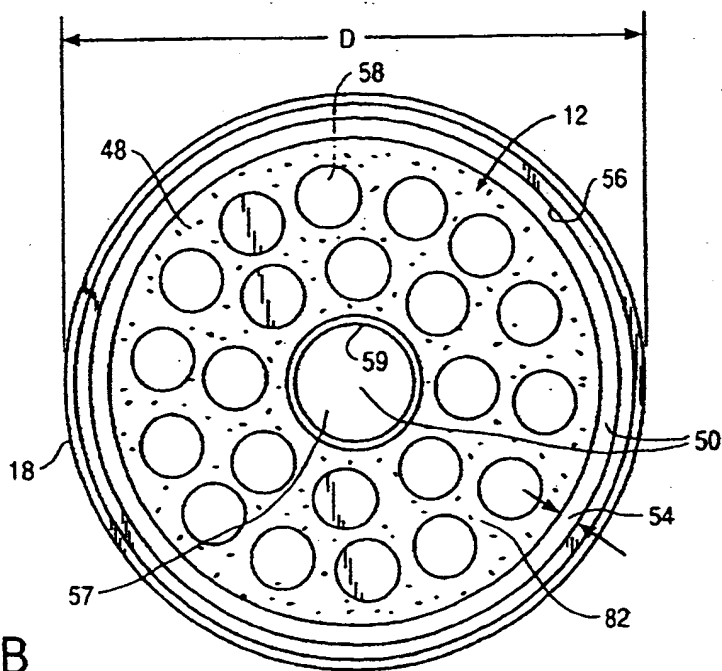


FIG. 2B

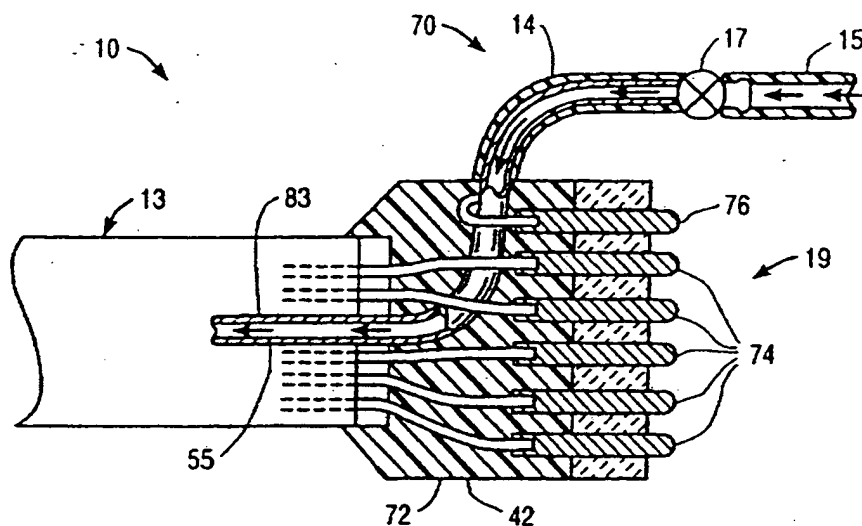


FIG. 2C

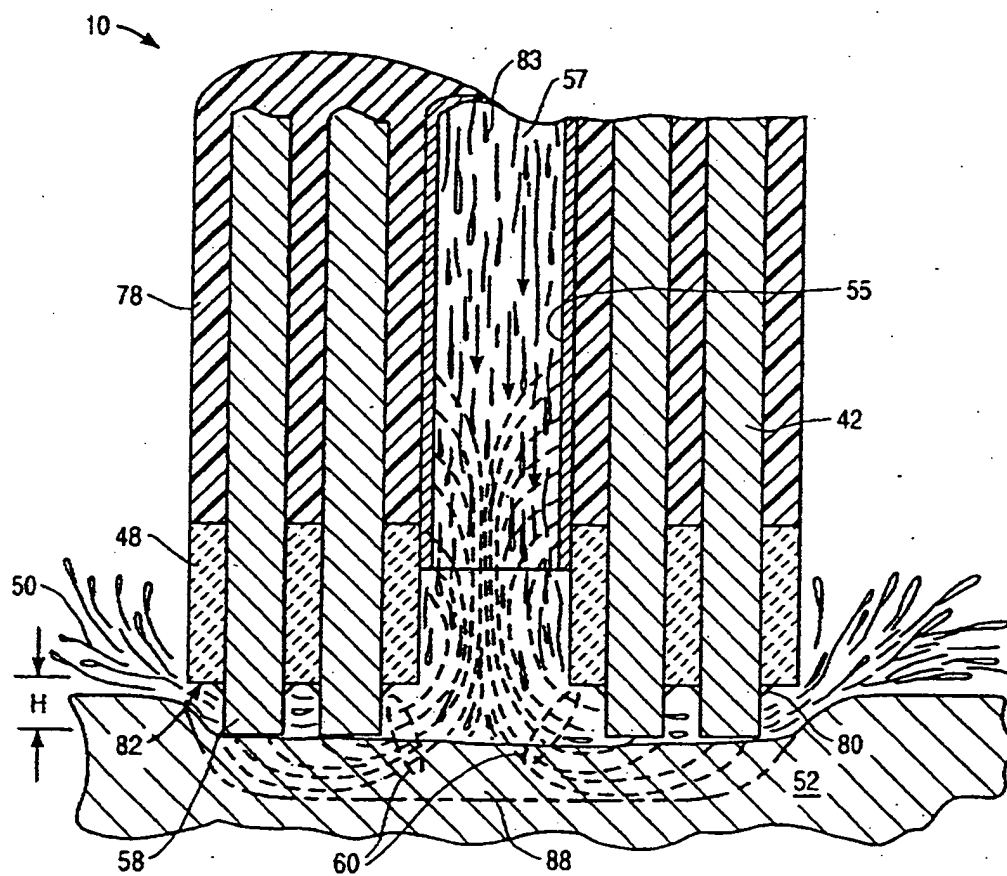


FIG. 3

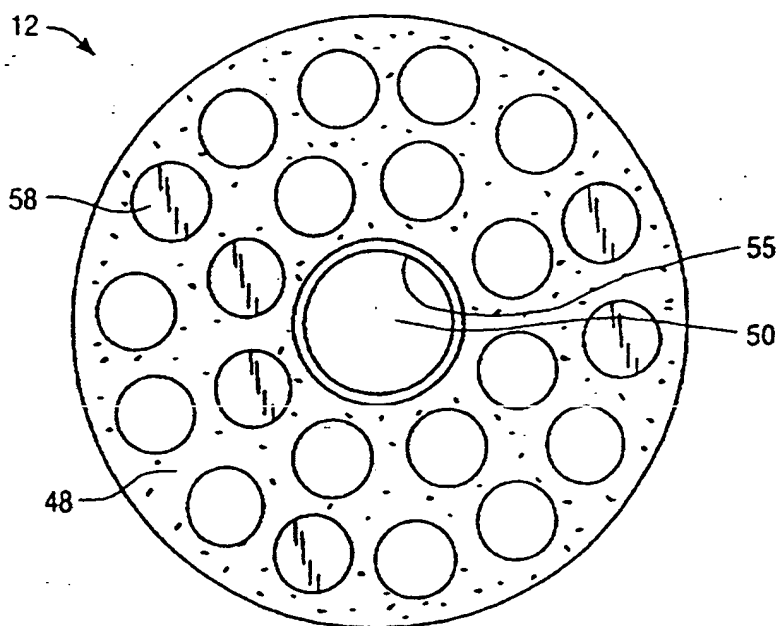


FIG. 4

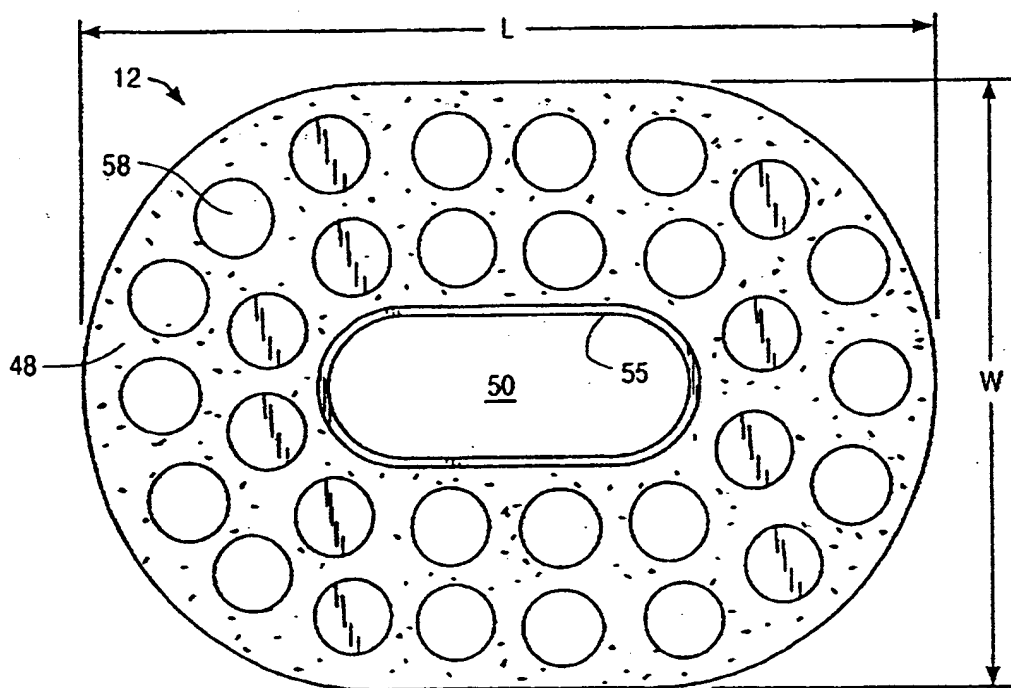


FIG. 5

A400.6

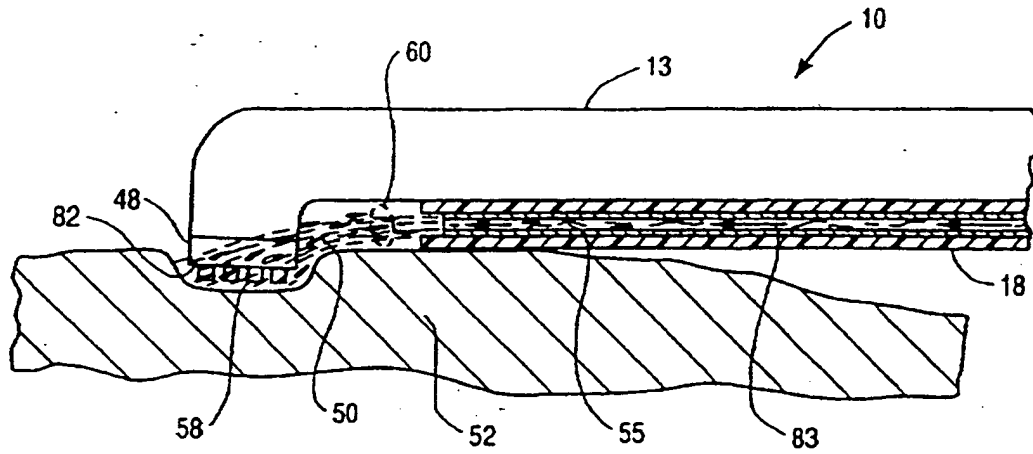


FIG. 6

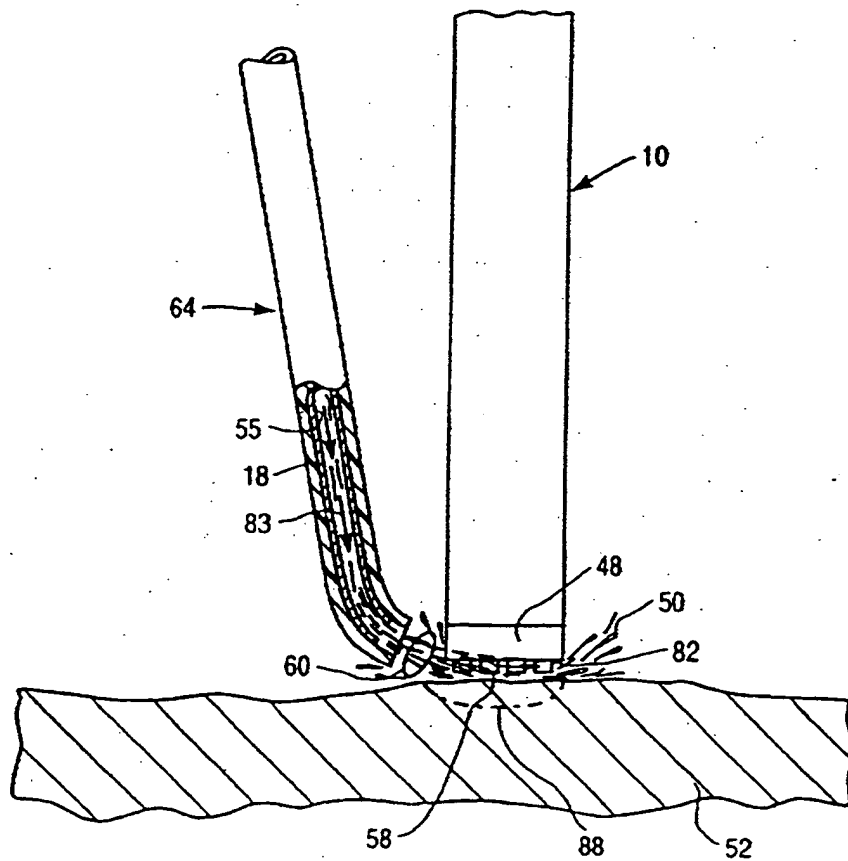


FIG. 7

A400.7

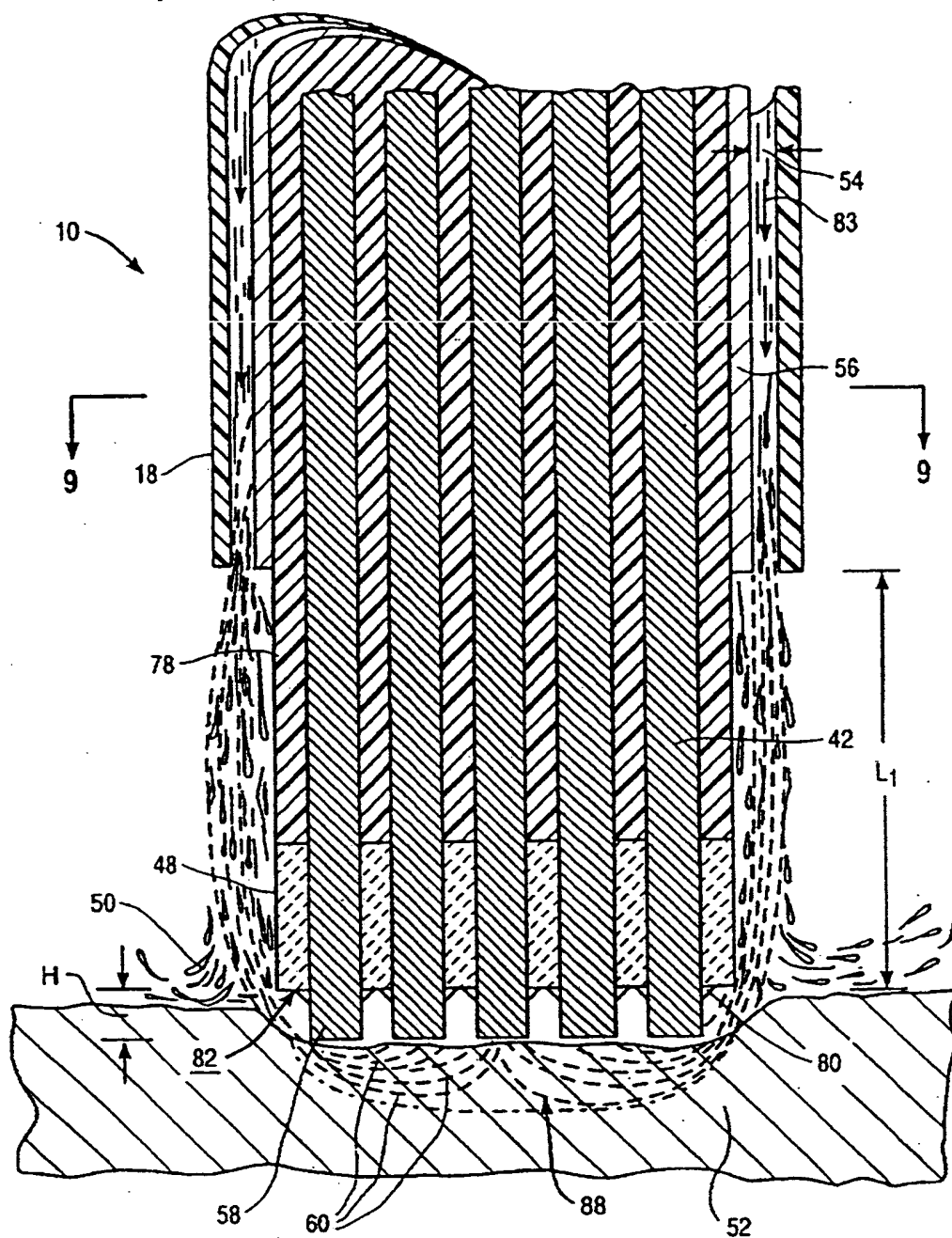


FIG. 8

A400.8

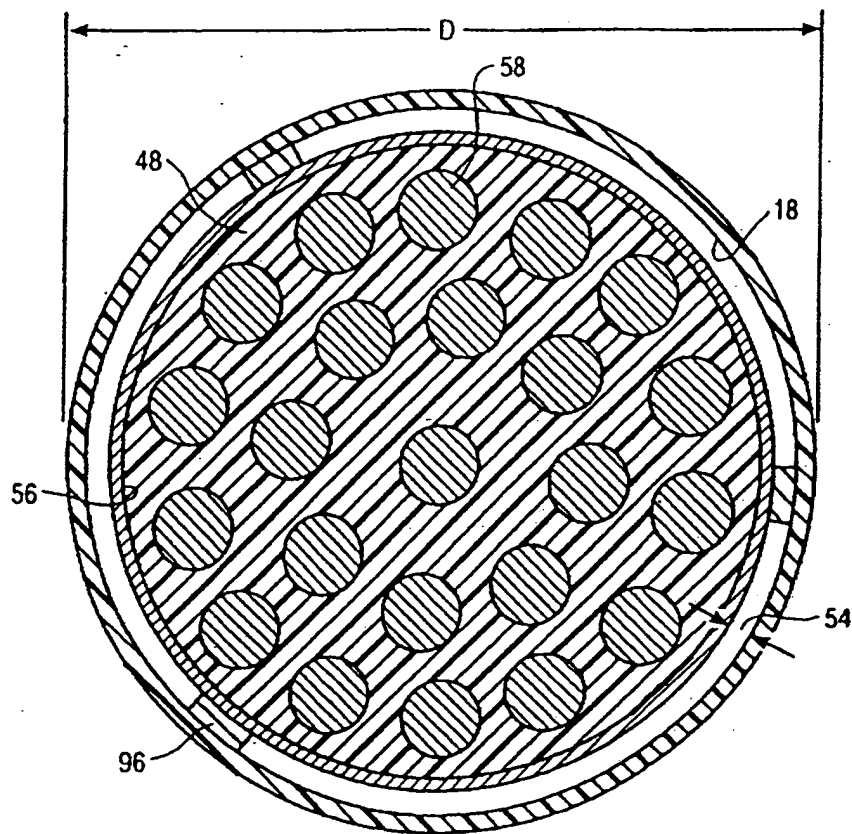


FIG. 9

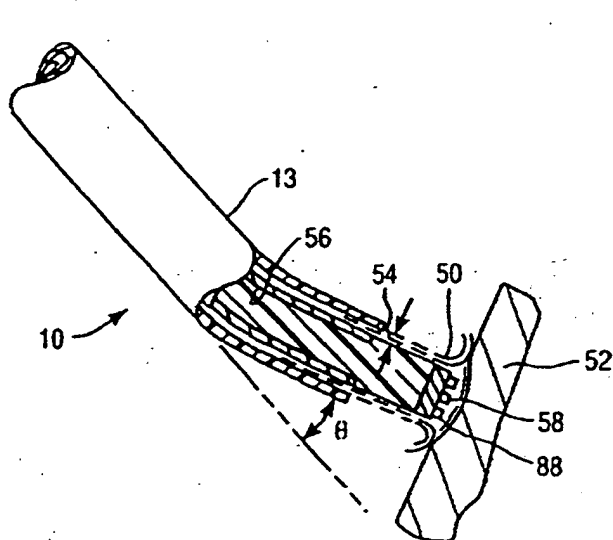


FIG. 10

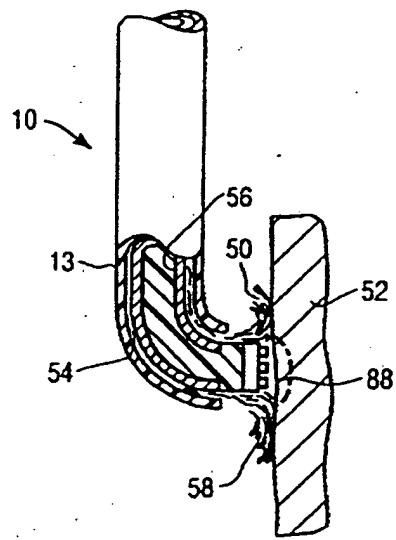


FIG. 11

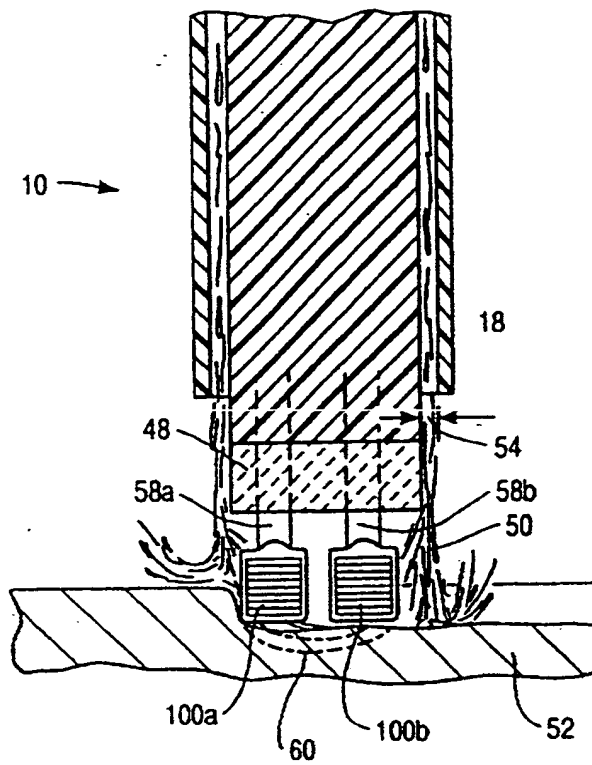


FIG. 12

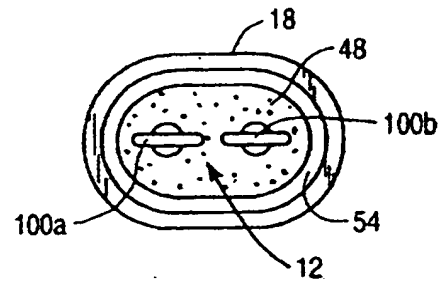


FIG. 13

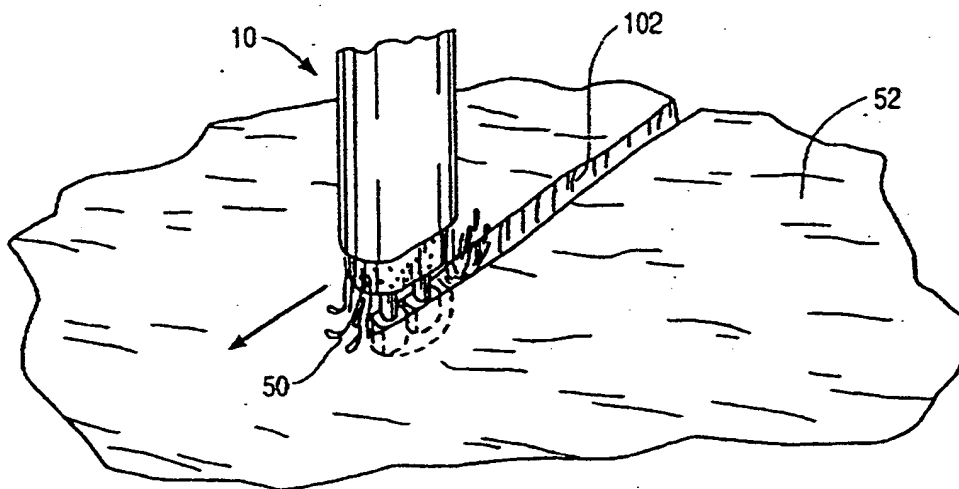


FIG. 14

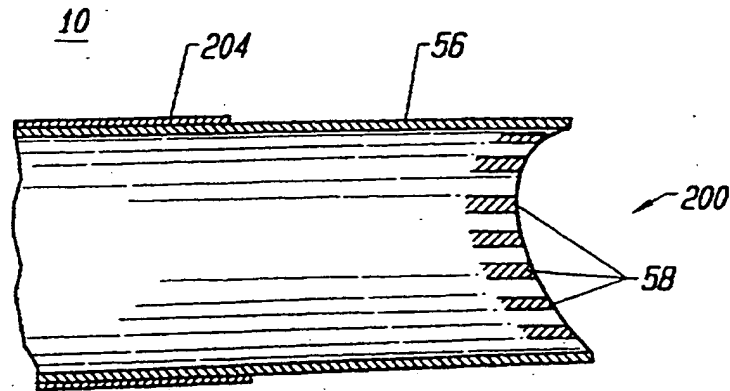


FIG. 15

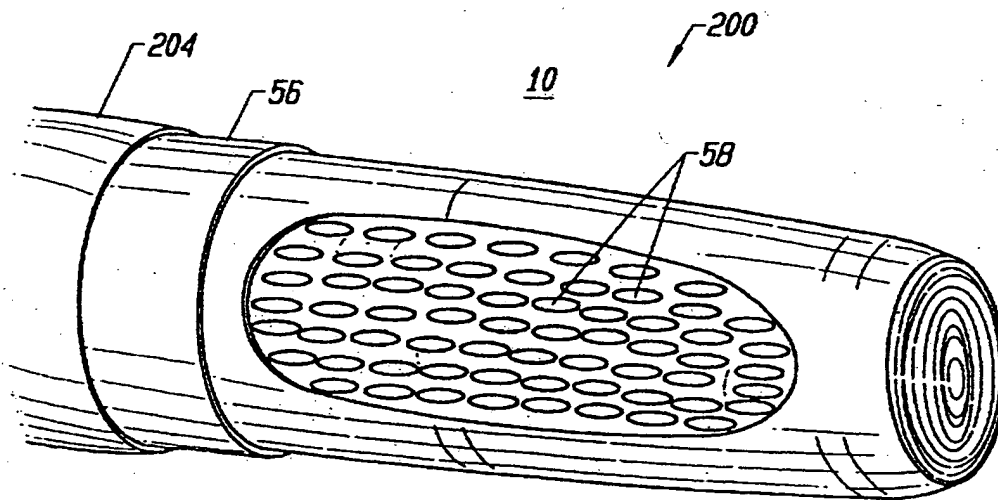
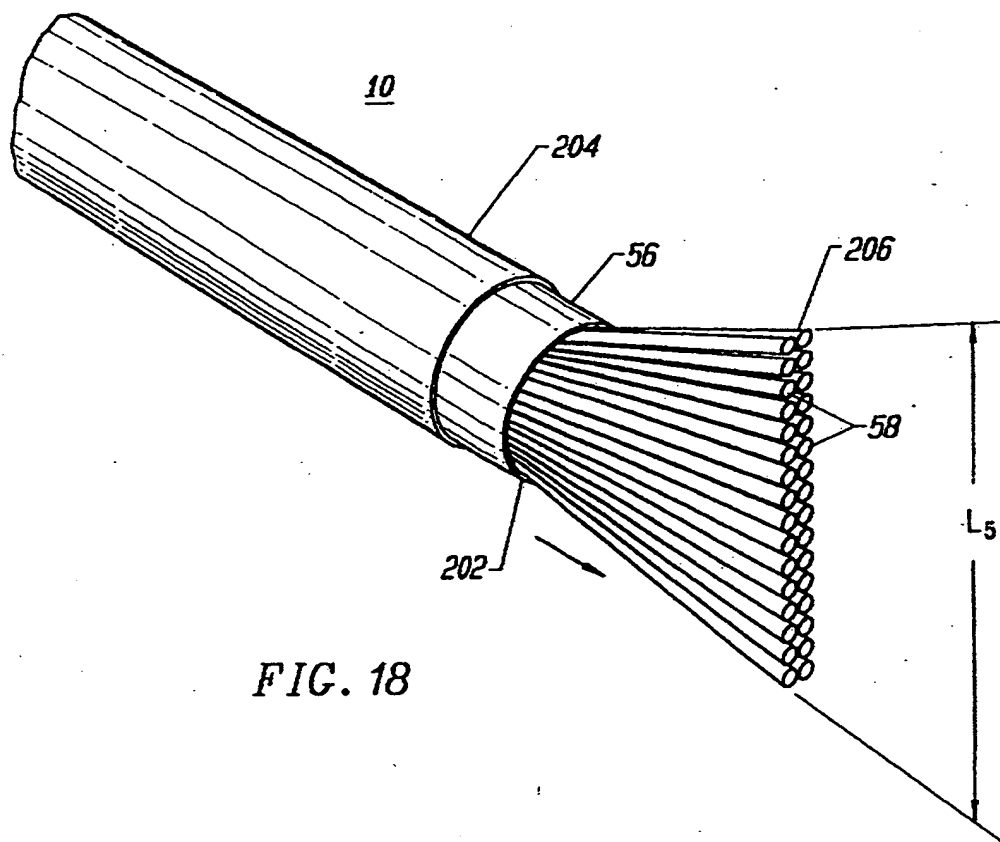
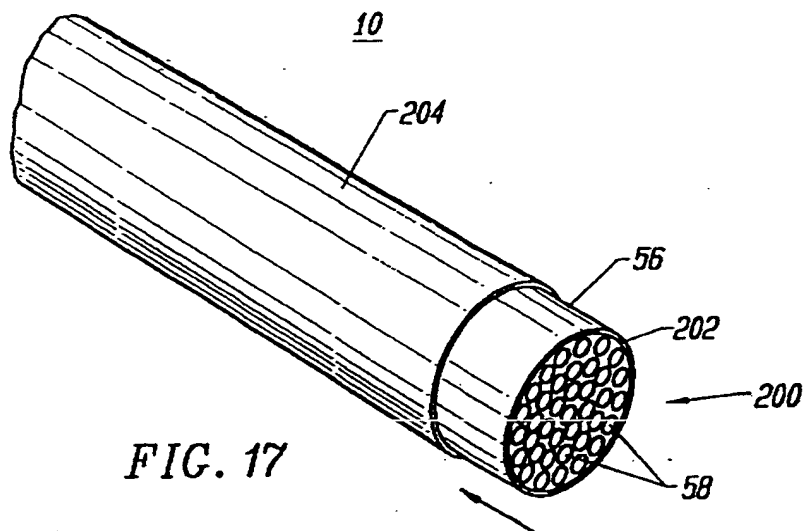


FIG. 16



SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

This is a Division of application Ser. No. 08/485,219 filed Jun. 7, 1995 pending, which is a continuation-in-part of application Ser. No. 08/446,767 filed on Jun. 2, 1995 and pending; which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993, now abandoned; which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992, now U.S. Pat. No. 5,366,443; which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992, now abandoned; the full disclosures of which are incorporated herein by reference.

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Additionally, electrosurgical ablation procedures, where tissue surfaces and volume may be reshaped, cannot be duplicated through other treatment modalities.

Current electrosurgical devices and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying surrounding tissue.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may

cause tissue desiccation or destruction at its contact point with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

In response to the various problems associated with electrosurgical procedures in electrically conductive environments, new methods and devices have been developed by the applicant. These methods and devices provide selective power delivery to the target tissue while minimizing power delivery to the surrounding electrically conductive irrigant. These methods are particularly useful in isotonic saline filled body cavities, such as arthroscopic, urologic or gynecologic cavities. The irrigant flooded body cavity provides good visibility, facilitates the removal of bubbles or other debris, minimizes the possibility of air embolism and protects certain tissue from dehydration. Such methods and devices are more fully described in previously filed, commonly assigned applications Ser. Nos. 08/059,681, 07/958,977 and 07/817,575, the full disclosures of which have been incorporated by reference.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth or the ablation and necrosis of diseased tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of tissue. These systems and methods should be capable of providing a direct return current path from the active electrode, through the target site, to the return electrode to minimize the dangers of electrical current flowing through undefined paths in the patient's body. The system should also be configured to minimize contact between the return electrode and surrounding tissue and to avoid current shorting between the active and return electrodes. Preferably, the system will be configured to apply high frequency voltage for the cutting and ablation of tissue in relatively dry environments, such as those encountered in oral, laparoscopic and open surgical procedures.

2. Description of the Background Art

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1: 242-246

and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

SUMMARY OF THE INVENTION

The present invention provides an apparatus and method for selectively applying electrical energy to structures within a patient's body. The apparatus and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, without requiring the tissue to be submerged in an electrically conducting irrigant, such as isotonic saline. The apparatus and method of the present invention are particularly useful for treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, and ablation and necrosis of diseased tissue, such as tumors.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into at least partial contact or close proximity with the target site. Electrically conducting liquid, such as isotonic saline, is directed through a fluid path past a return electrode and to the target site to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The above described method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, laparoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In laparoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and to shield the return electrode from tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner passage

for flow of electrically conducting liquid therethrough. The liquid is directed through the return electrode and over the active electrode to thereby provide a return current flow path between the tissue target site and the return electrode.

In a preferred aspect of the invention, the active electrode comprises an electrode array having a plurality of electrically isolated electrode terminals disposed over a contact surface, which may be a planar or non-planar surface and which may be located at the distal tip or over a lateral surface of the shaft, or over both the tip and lateral surface(s). The electrode array will include at least two and preferably more electrode terminals, and may further comprise a temperature sensor. In a preferred aspect, each electrode terminal will be connected to the proximal connector by an electrically isolated conductor disposed within the shaft. The conductors permit independent electrical coupling of the electrode terminals to a high frequency power supply and control system with optional temperature monitor for operation of the probe. The control system preferably incorporate active and/or passive current limiting structures, which are designed to limit current flow when the associated electrode terminal is in contact with a low resistance return path back to the return electrode.

The use of such electrode arrays in electrosurgical procedures is particularly advantageous as it has been found to limit the depth of tissue necrosis without substantially reducing power delivery and ablation rates. The voltage applied to each electrode terminal causes electrical energy to be imparted to any body structure which is contacted by, or comes into close proximity with, the electrode terminal, where a current flow through all low electrical impedance paths is preferably but not necessarily limited. It will be appreciated that such low impedance paths generally occur when an electrode terminal does not contact or come into close proximity with the body structure, but rather is in contact with a low impedance environment, such as the saline, or other electrolyte being introduced past the return electrode. The presence of an electrolyte provides a relatively low impedance path back to the common or return electrode.

The apparatus and method of the present invention provide a number of advantages, particularly in respect to the ablation or cutting of tissue. The ability to control current flow through individual electrode terminals minimizes power dissipation into the surrounding medium. Limited power dissipation, in turn, permits the use of electrolytic irrigants, such as isotonic saline, to create a current flow path between the active electrode terminals and the return electrode. The isotonic saline may also be used to simultaneously irrigate the surgical site, which provides a number of well known physiological advantages. In addition, the ability to operate in a bipolar or quasi-bipolar mode reduces the risk of unwanted electrical stimulation from return current flowing through the patient's body, which can cause muscle spasms and can limit the depth of tissue necrosis during ablative resection.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12; and

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue.

FIG. 15 illustrates another alternative electrode surface configuration for the electrosurgical probe of FIG. 1.

FIG. 16 illustrates a second alternative electrode surface configuration.

FIGS. 17 and 18 illustrate an electrosurgical probe having an electrode surface which can be transformed from a flat, circular array (FIG. 17) to an elongate, linear array (FIG. 18) suitable for use in surgical cutting.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an apparatus and method for selectively applying electrical energy to a target location within a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

The present invention uses an electrode array including a plurality of independently current-limited and/or power-

controlled electrode terminals distributed over a distal contact surface of a probe to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an electrode array near its distal end. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the electrode array and permit the treating physician to manipulate the array from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently is in the range from 1 to 10 mm. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) against or in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in contact or close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

Each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g.,

blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof.

The tip region of the probe is thus composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to of the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the said common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor or other connective tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm²,

and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition is tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electro-surgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

The rate of energy delivery to the target tissue is controlled by the applied voltage level and duty cycle of the voltage pulse. The use of high frequency current minimizes induced stimulation of muscle tissue or nerve tissue in the vicinity of the body structure being treated. In addition, high frequencies minimize the risk of interfering with the natural pacing of the heart in circumstances where the probe of the present invention is used near the heart.

The power applied to the common electrode and the electrode array will be at high or radio frequency, typically between about 20 kHz and 20 MHz, usually being between about 30 kHz and 2 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 10 volts to 500 volts. Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired surface temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate

average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, open surgery or other endoscopic surgery procedure.

The power source will be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 20 nH to 5000 nH, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, which has already been incorporated herein by reference. Additionally, current limiting resistors may be selected having a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode from being energized during given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this

example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

The electrode array is formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and array of active electrodes. In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of laparoscopic or endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Electrode array contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, or virtually any other regular or irregular shape. Most commonly, the electrode arrays will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the electrode arrays may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT/US94/05168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 1 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.5 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3). As described above, electrode terminals which are flush with the surface, or protrude by a minimum distance, will provide less aggressive ablation and are particularly suitable for smoothing of treated tissue surfaces and providing hemostasis to inhibit or prevent bleeding of treated surfaces.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, platinum alloys, titanium, titanium alloys and the like. Platinum is the preferred choice for electrode terminal material since it is biocompatible, has a low erosion rate, and can be readily fabricated and attached to conductors 42 within the shaft 13 of electrosurgical probe 10. As shown in FIG. 2B, the electrode terminals 58 are anchored in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes are then bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the alumina matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.25 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 1 mm to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyamide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this current path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. Liquid paths 83 are formed by annular gap 54 between outer return electrode 56 and tubular support member 78 and an inner lumen 57 within an inner tubular member 59. The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins

76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83 through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.25 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screw-driver shape. The screwdriver shape provides a greater

amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgical team then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

Yet another configuration for tip 200 of probe 10 is shown in FIG. 15 wherein a concave or wedge-shaped arrangement of electrodes 58 is provided to facilitate good contact with target tissue which can be embraced by said concave or wedge-shaped opening. As before, the return electrode 56 may be positioned proximal to probe tip 200.

Still yet another configuration for tip 200 of probe 10 is shown in FIG. 16 wherein electrodes 58 terminate on the side of the generally tubular (e.g., cylindrical) surface proximal to the distal end of probe 10. This configuration allows the electrode array to be brought into contact with target tissue surfaces which are tangent to the tubular surface of probe 10. As before, return electrode 56 may be positioned proximal to probe tip 200.

Another configuration for tip 200 of probe 10 is shown in FIGS. 17 and 18 and features a variable tip configuration which can be adjusted during the course of use of said probe 10. By way of example, tip 200 of probe 10 can be a cylindrical array of electrodes 58 which conforms to the cylindrical geometry of a rigid support member or cannula 202. The distal end of said cannula 202 may also serve as the common electrode 56 which is insulated in regions proximal to the tip region by an electrically insulating member 204. Referring now to FIG. 18, by extending the flexible array of electrodes 58 beyond the orifice of the cannula 202, an alternative electrode configuration can be obtained. By way of example, by placing a flat yet flexible member 206 between electrodes 58 as shown in FIG. 18, the electrode array can assume a flat "blade" shape configuration made up of a multiplicity of individual electrodes 58, each electrically insulated from all other electrodes. Such a configuration change may be advantageous if, after the insertion of the probe through a circular introduction port, the user can change the shape of the electrode array to achieve a flat "blade" shaped array whose width L_2 may be substantially greater than the circular electrode array configuration shown in FIG. 17. The increased width L_2 of the electrode array in FIG. 18 will provide the means for faster cutting through the target tissue since cutting depends primarily on the major dimension of the electrode array, either the diameter of the array (as shown in FIG. 17) or the width, L_2 of the array (as shown in FIG. 18). If the array width in FIG. 18 is three times as greater as the array diameter in FIG. 17, then the rate of cutting of the target tissue can be increased by

approximately a factor of three. An additional benefit is that the depth of necrosis in tissue on either side of the cut made with the flat electrode configuration will be less than with the larger array used in a circular configuration.

What is claimed is:

1. An electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply, the system comprising:

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft for electrically coupling the electrode terminal to the electrosurgical power supply; a return electrode adapted to be electrically coupled to the electrosurgical power supply; and

a fluid delivery element defining a fluid path in electrical contact with the return electrode and the electrode terminal, the fluid path having an inlet adapted to be fluidly coupled to the electrically conducting fluid supply for directing fluid along the fluid path to generate a current flow path between the return electrode and the electrode terminal.

2. An electrosurgical system as in claim 1, wherein the return forms a portion of the shaft of the electrosurgical probe.

3. An electrosurgical system as in claim 2 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and a body structure at the target site when the electrode terminal is positioned in close proximity or in partial contact with the body structure.

4. An electrosurgical system as in claim 2, wherein the return electrode is an inner tubular member and the fluid delivery element comprises an axial lumen within the return electrode, the axial lumen forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

5. An electrosurgical system as in claim 2, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member, wherein the fluid delivery element comprises an axial passage between the insulating member and the return electrode, the axial passage forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

6. An electrosurgical system as in claim 1 wherein the fluid delivery element comprises a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

7. An electrosurgical system as in claim 6 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

8. An electrosurgical system as in claim 7 wherein the fluid supply instrument comprises an electrically insulating sheath around the tubular member, the tubular member being proximally recessed from a distal end of the sheath.

9. An electrosurgical system as in claim 1 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality of electrically isolated electrode terminals disposed over a contact surface.

10. The electrosurgical system of claim 9 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independently controlling current flow to each of the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

11. The electrosurgical system of claim 9 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

12. The electrosurgical system of claim 9 wherein the distal surface of the array of electrode terminals is circular in shape with a diameter in the range from 1 mm to 10 mm.

13. The electrosurgical system of claim 9 wherein the shape of the distal surface of the array of electrode terminals has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

14. The electrosurgical system of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

15. The electrosurgical system of claim 1 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

16. The electrosurgical system of claim 1 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

17. The electrosurgical system of claim 16 wherein the electrically conducting fluid between the electrode terminal and the return electrode has an inherent capacitance, wherein the inherent capacitance of the tissue and electrically conducting fluid between the electrode terminal and the return electrode combined with the current limiting element together form a series resonant output circuit.

18. The system of claim 17 wherein the series resonant circuit has a resonant frequency that varies with changes in the inherent capacitance between the electrode terminal and the return electrode.

19. The electrosurgical system of claim 16 wherein the current limiting element is an active current limiting element for actively limiting current to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

20. The electrosurgical system of claim 19 wherein the active current limiting element measures current flow for a given applied voltage.

21. The electrosurgical system of claim 19 wherein the active current limiting element comprises an impedance sensor for indicating an electrical impedance less than a threshold level.

22. The electrosurgical system of claim 16 wherein the current limiting element is a passive current limiting element selected from the group consisting essentially of inductors, capacitors, resistors and combinations thereof.

23. The electrosurgical system of claim 1 wherein the height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0 to 2 mm.

24. The electrosurgical system of claim 1 wherein the distance between the most distal portion of the return electrode and the most proximal portion of the electrode terminal is in the range from 0.5 to 10 mm.

25. The electrosurgical system of claim 1 wherein the distal surface of the electrode terminal has a shape selected

from the group consisting essentially of flat, concave, convex, hemispherical, linear (in-line), pyramidal, conical and cylindrical.

26. The electrosurgical system of claim 1 wherein the fluid delivery element further comprises a control valve positioned on the shaft of the probe for controlling flow of the electrically conducting fluid through the fluid path.

27. The electrosurgical system of claim 1 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

28. The electrosurgical system of claim 1 further comprising an insulating matrix surrounding and supporting the electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

29. The electrosurgical system of claim 28 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

30. The electrosurgical system of claim 1 wherein the electrode terminal and the return electrode are configured to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal when high frequency voltage is applied between the electrode terminal and the return electrode in the presence of electrically conducting fluid.

31. The electrosurgical system of claim 1 wherein the electrically conducting fluid is selected from the group consisting essentially of blood and electrolytic irrigants.

32. The electrosurgical system of claim 1 wherein the electrically conducting liquid comprises saline.

33. The electrosurgical system of claim 1 wherein the electrode terminal has a distal portion configured for generating high electric field intensities sufficient to cause molecular disintegration of a body structure at the target site.

34. The electrosurgical system of claim 1 further comprising a temperature sensor adjacent the electrode terminal, the temperature sensor being adapted to be electrically coupled to the high frequency voltage source such that power delivery to the electrical terminal is limited if the measured temperature exceeds a threshold value.

35. The electrosurgical system of claim 34 wherein the temperature sensor is integral with the electrode terminal.

36. The electrosurgical system of 1 wherein the distal surface of the electrode terminal is circular in shape with a diameter in the range from 1 mm to 10 mm.

37. The electrosurgical system of claim 1 wherein the shape of the distal surface of the electrode terminal has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

38. The system of claim 1 wherein the electrode terminal is configured for the cutting of tissue.

39. The system of claim 1 wherein the probe comprises a concave-shaped portion, the electrode terminal being disposed within the concave-shaped portion such that the concave-shaped portion at least partially surrounds the target site when the electrode terminal is brought into at least partial contact or close proximity with the target site.

40. The system of claim 1 wherein the probe comprises a lateral surface, the electrode terminal being positioned on the lateral surface such that the electrode terminal may be brought into at least partial contact or close proximity with the tissue surfaces which are substantially tangent to the electrosurgical probe.

41. The system of claim 1 wherein the electrode terminal and the return electrode are configured, upon the application

of sufficient voltage therebetween, to effect the ablation of tissue adjacent the electrode terminal such that a portion of said tissue is volumetrically removed.

42. The system of claim 1 wherein the electrode terminal is disposed at the distal tip of the electrosurgical probe.

43. The system of claim 42 wherein the return electrode is disposed proximally of the electrode terminal on the electrosurgical probe.

44. The system of claim 1 wherein the electrode terminal is a flexible electrode terminal disposed at the distal tip of the probe, the flexible electrode terminal being extendable relative to the distal tip of the probe.

45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply; and

an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.

46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.

47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.

48. An electrosurgical system as in claim 46, wherein the return electrode is an inner tubular member defining an axial lumen within the return electrode, the axial lumen having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

49. An electrosurgical system as in claim 46, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member defining an axial passage between the insulating member and the return electrode, the axial passage having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

50. An electrosurgical system as in claim 45 further including a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

51. An electrosurgical system as in claim 50 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

52. The electrosurgical system of claim 51 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independent controlling current flow through the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

53. An electrosurgical system as in claim 45 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality

of electrically isolated electrode terminals disposed over a contact surface.

54. The electrosurgical system of claim 53 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

55. The electrosurgical system of claim 45 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

57. The electrosurgical system of claim 45 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

58. The electrosurgical system of claim 45 wherein the frequency of the voltage applied between the return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz.

59. The electrosurgical system of claim 45 wherein the voltage applied between the electrode terminal and the return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS).

60. The electrosurgical system of claim 45 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

61. The electrosurgical system of claim 45 further comprising an insulating matrix surrounding and supporting

electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

62. The electrosurgical system of claim 45 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

63. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply;

an electrically conducting fluid supply;

a fluid delivery element defining a fluid path electrically coupled to the electrode terminal for directing electrically conducting fluid to the target site and the electrode terminal to substantially surround the electrode terminal with electrically conducting fluid and to locate electrically conducting fluid between the electrode terminal and the target site.

64. The system of claim 63 wherein the return electrode is located on a surface of the patient's body.

* * * * *



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(12) **REEXAMINATION CERTIFICATE (4794th)**
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Eggers et al.

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(54) **SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION**

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(51) Int. Cl.⁷ **A61M 37/00**
(52) U.S. Cl. **604/114; 604/22**
(58) Field of Search **604/22, 43, 48,
604/113, 114, 264, 271; 606/27-31, 32-49**

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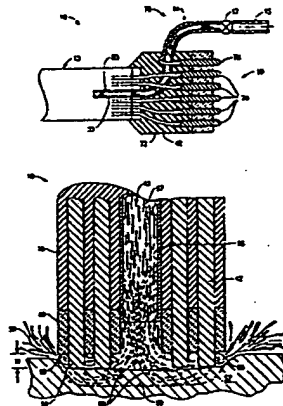
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Primary Examiner—Manuel Mendez

(57) **ABSTRACT**

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (12) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (55, 56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the target site and the return electrode so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the return electrode and the target site.



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**REEXAMINATION CERTIFICATE
ISSUED UNDER 35 U.S.C. 307**

NO AMENDMENTS HAVE BEEN MADE TO
THE PATENT

2

AS A RESULT OF REEXAMINATION, IT HAS BEEN
DETERMINED THAT:
The patentability of claims 1-64 is confirmed.

* * * * *

A400.26



US005697882A

United States Patent [19]

Eggers et al.

[11] Patent Number: 5,697,882

[45] Date of Patent: Dec. 16, 1997

[54] SYSTEM AND METHOD FOR
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[21] Appl. No.: 561,958

[22] Filed: Nov. 22, 1995

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which is a continuation-in-part of Ser. No. 59,681, May 10,
1993, abandoned, which is a continuation-in-part of Ser. No.
958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a
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[52] U.S. Cl. _____ 604/114; 604/22

[58] Field of Search _____ 604/114, 22, 28,
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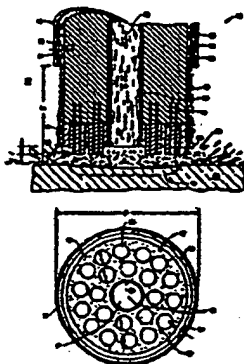
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[57] ABSTRACT

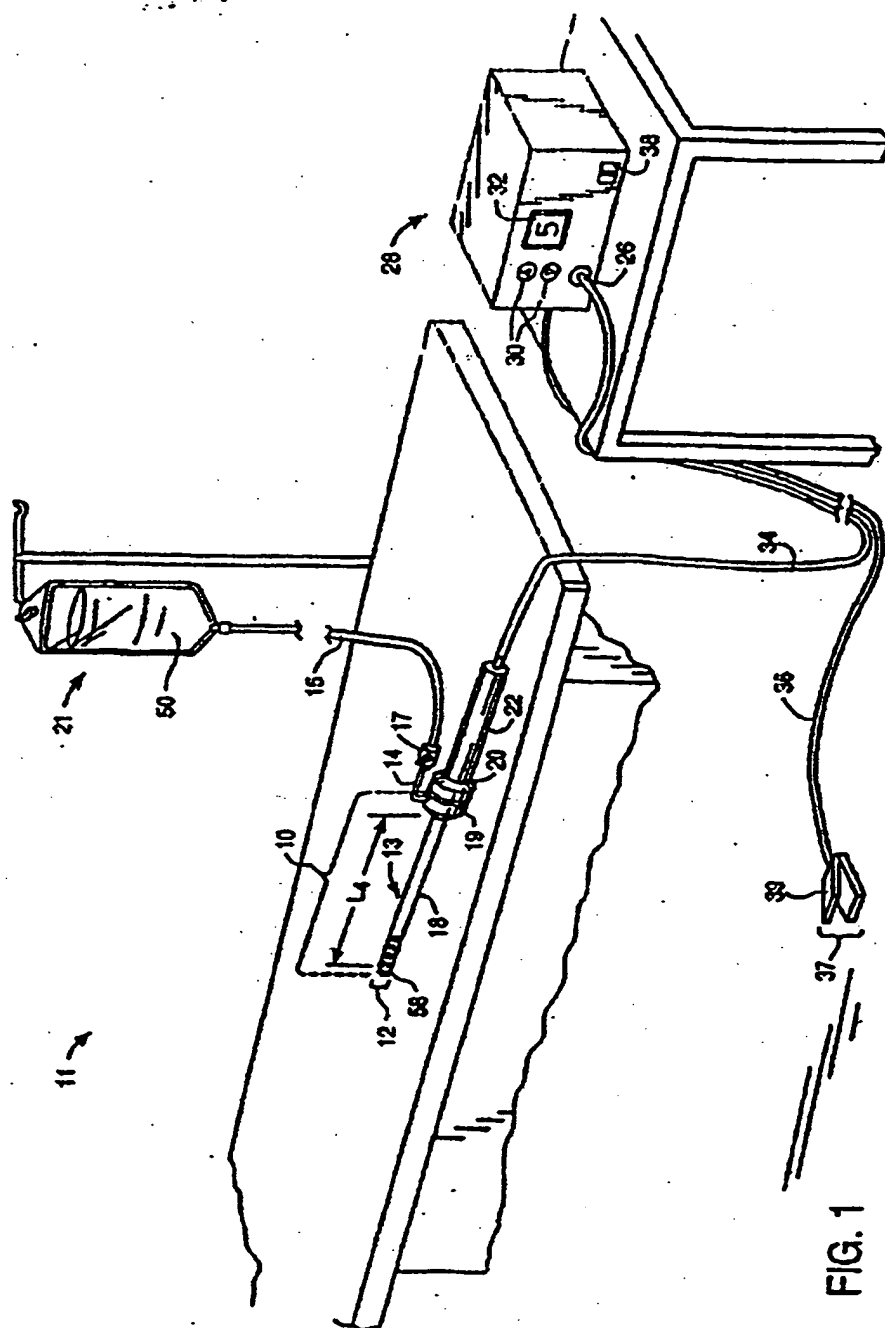
An electrosurgical probe (10) comprises a shaft (13) having an electrode array (58) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (26). The shaft includes a return electrode (56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the return electrode and the electrode array so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the active and return electrodes.

56 Claims, 17 Drawing Sheets



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5,282,797	2/1994	Chen	606/9	5,389,096	2/1995	Alta et al.	606/15
5,290,273	3/1994	Tan	606/9	5,423,803	6/1995	Tankovich	606/9
				5,445,634	8/1995	Keller	606/9
				5,569,242	10/1996	Lux et al.	606/42



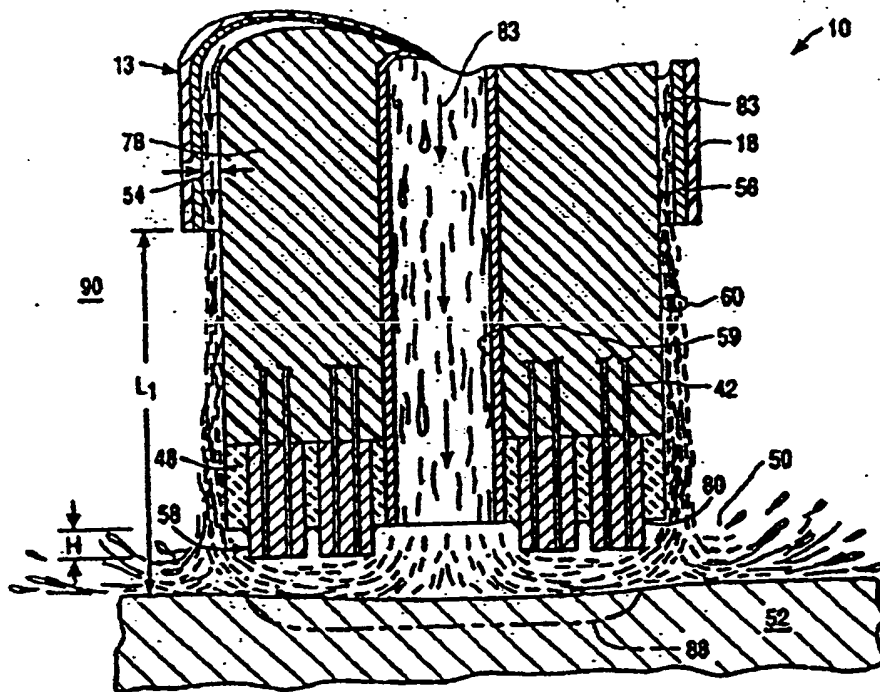


FIG. 2A

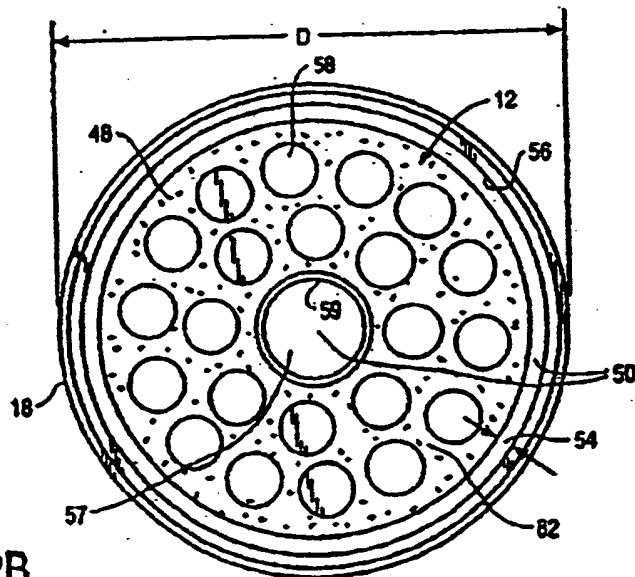
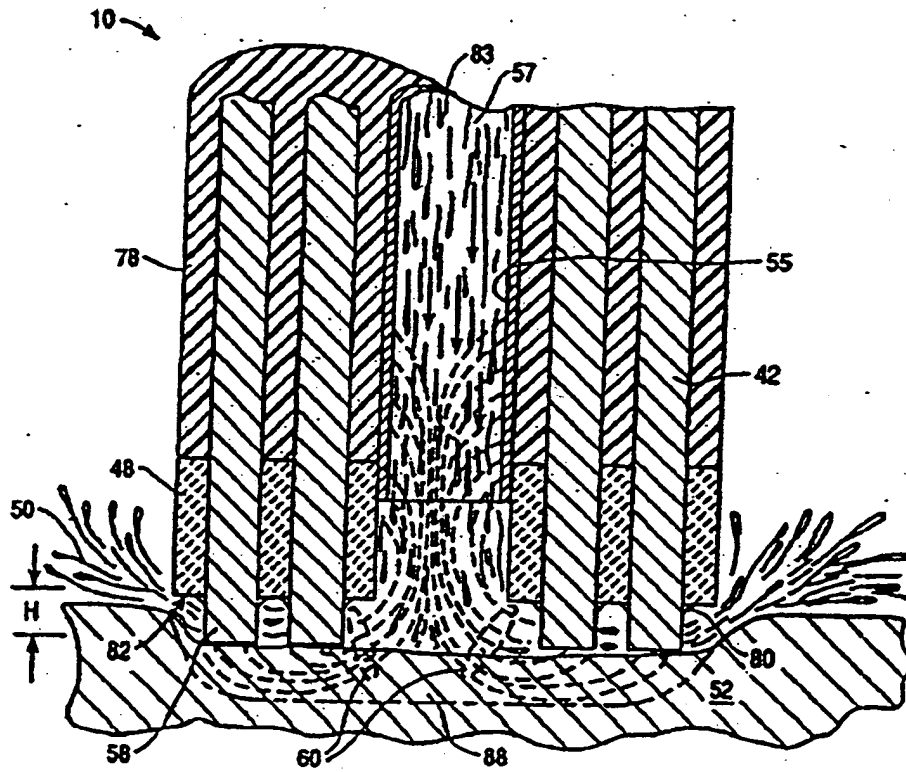
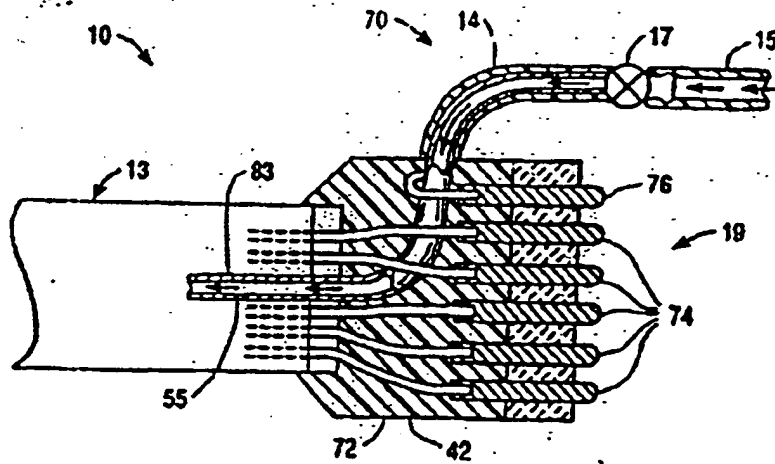


FIG. 2B



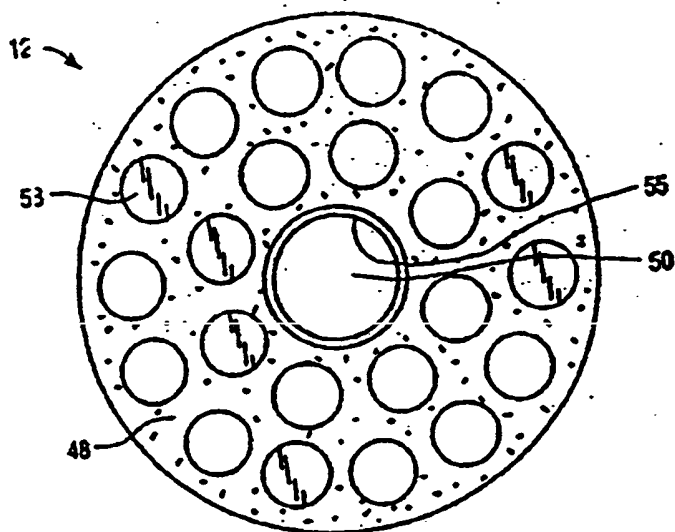


FIG. 4

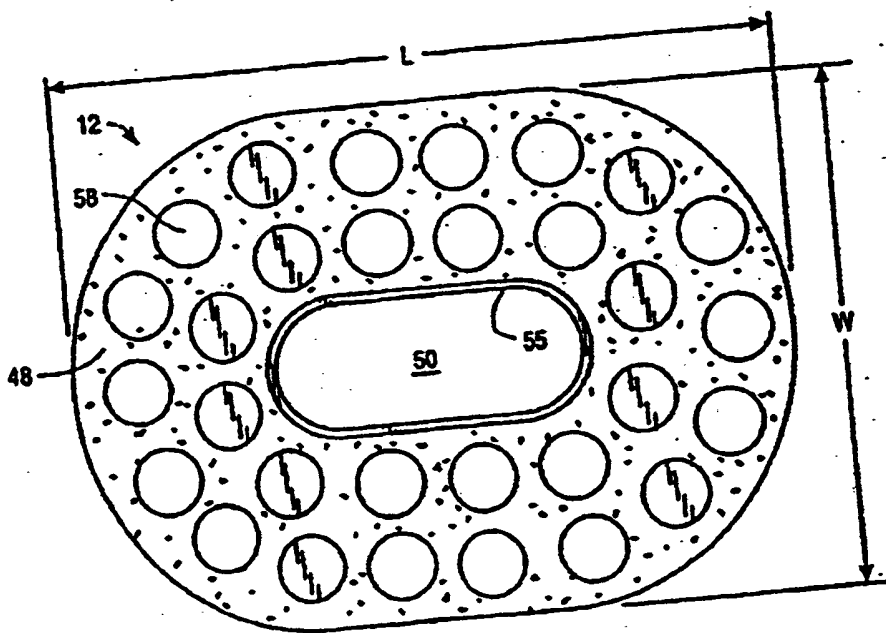


FIG. 5

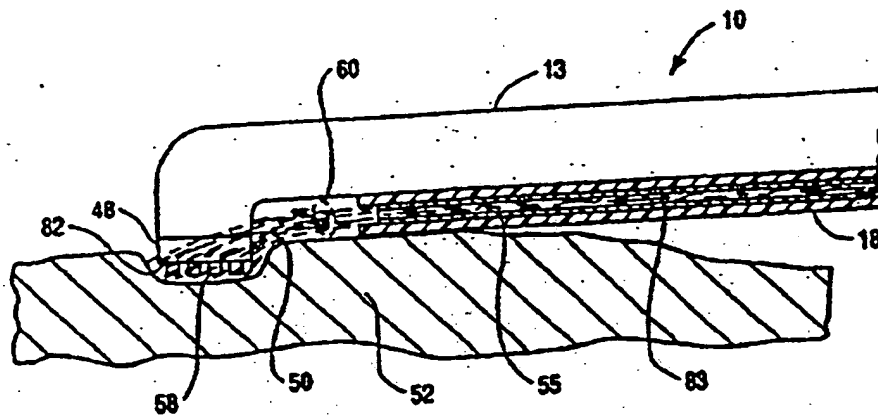


FIG. 6

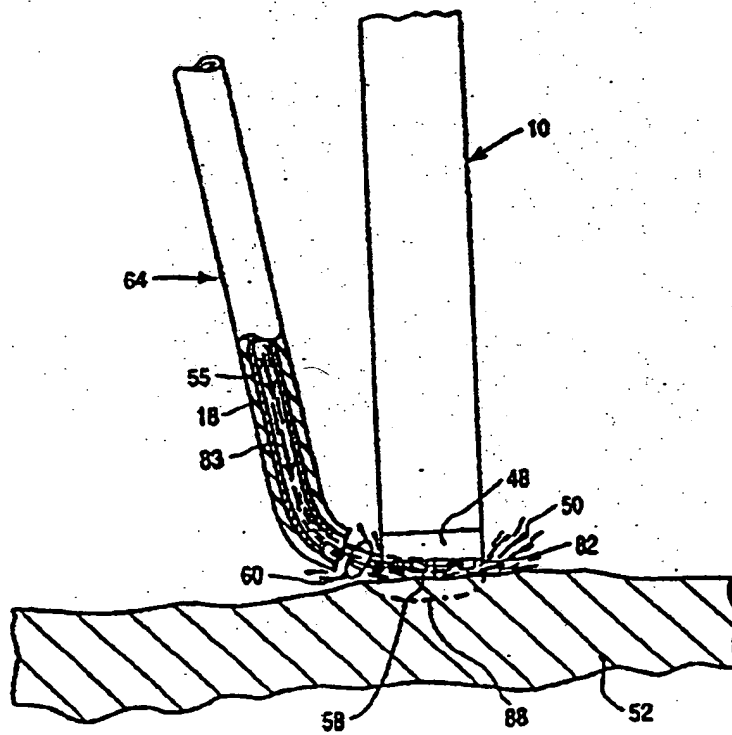


FIG. 7

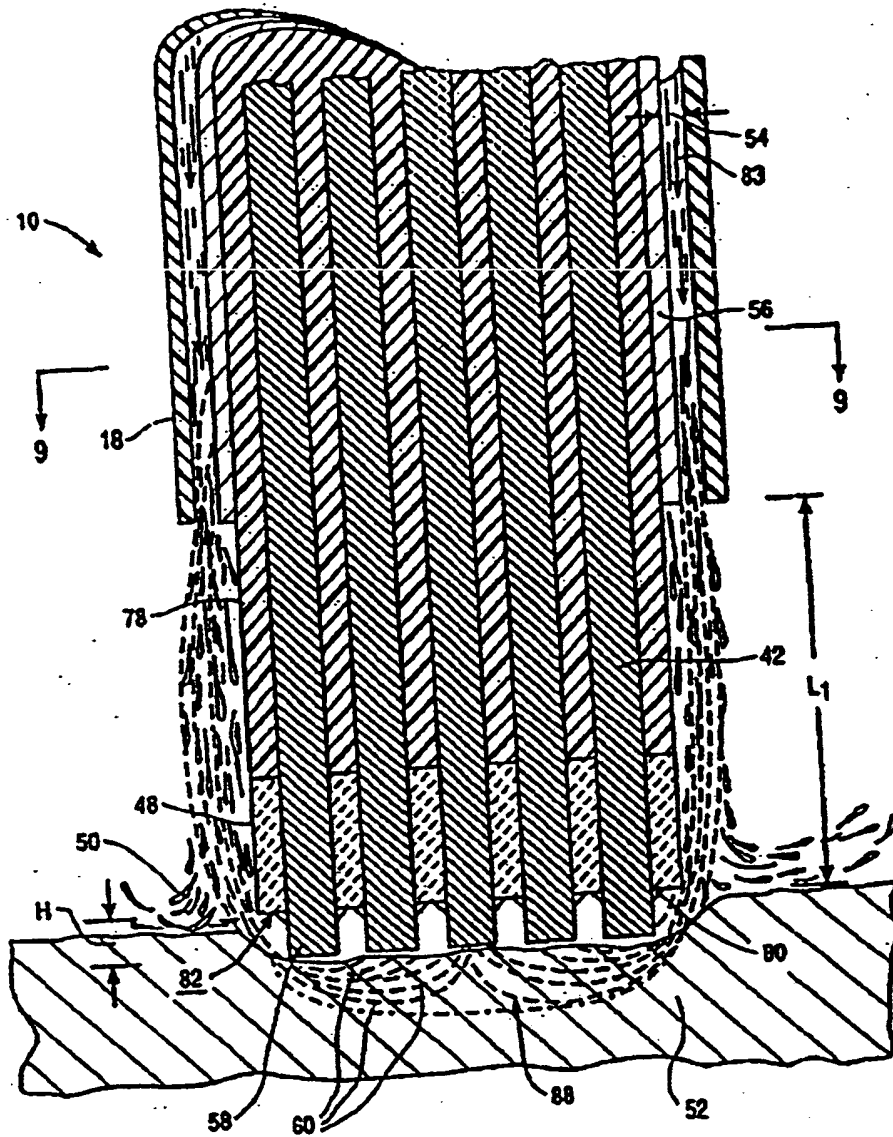


FIG. 8

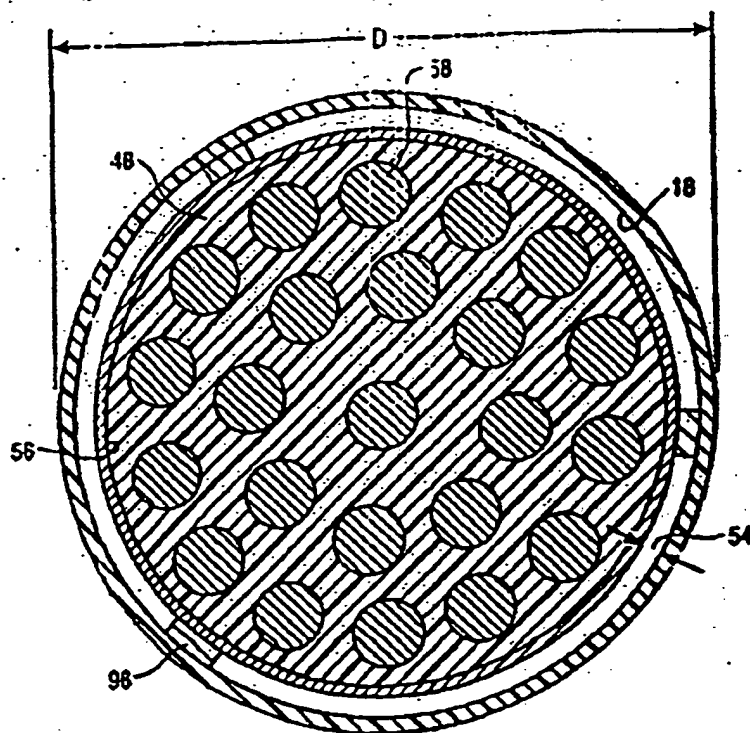


FIG. 9

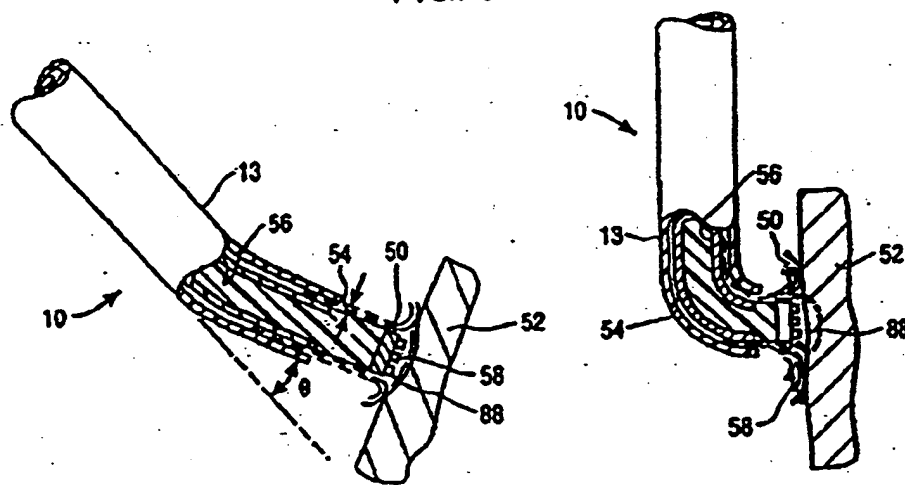


FIG. 10

FIG. 11

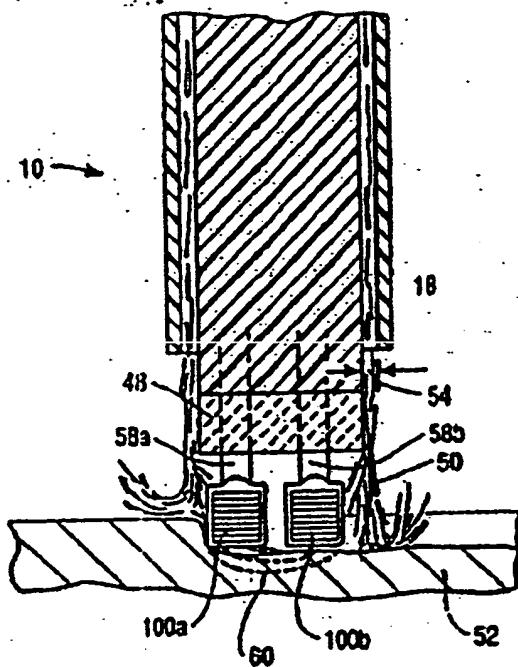


FIG. 12

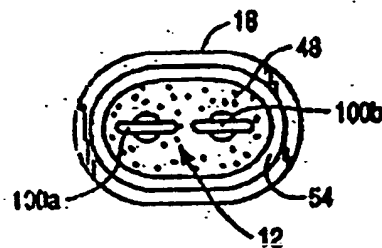


FIG. 13

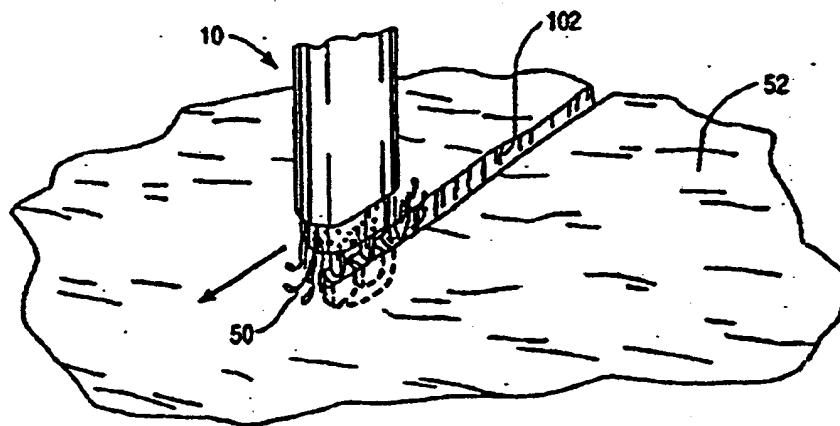


FIG. 14

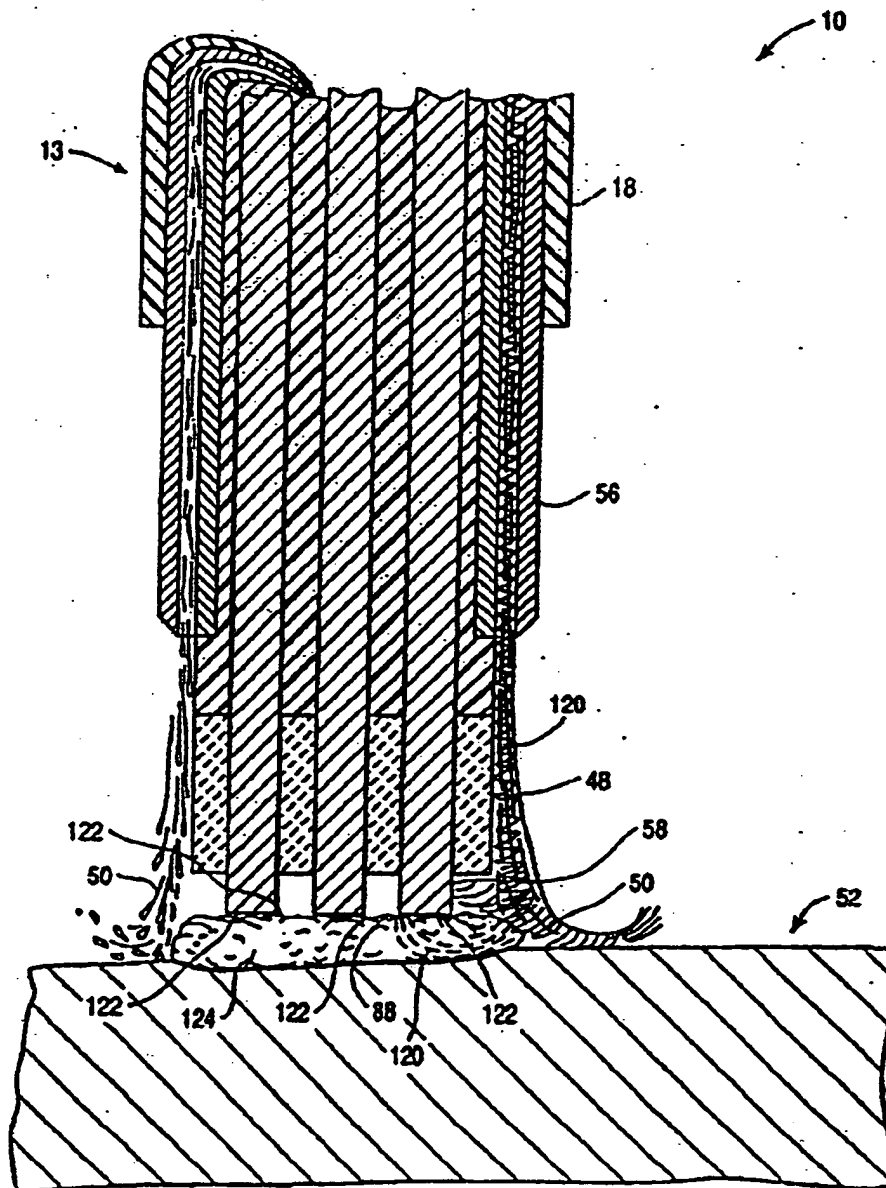


FIG. 15

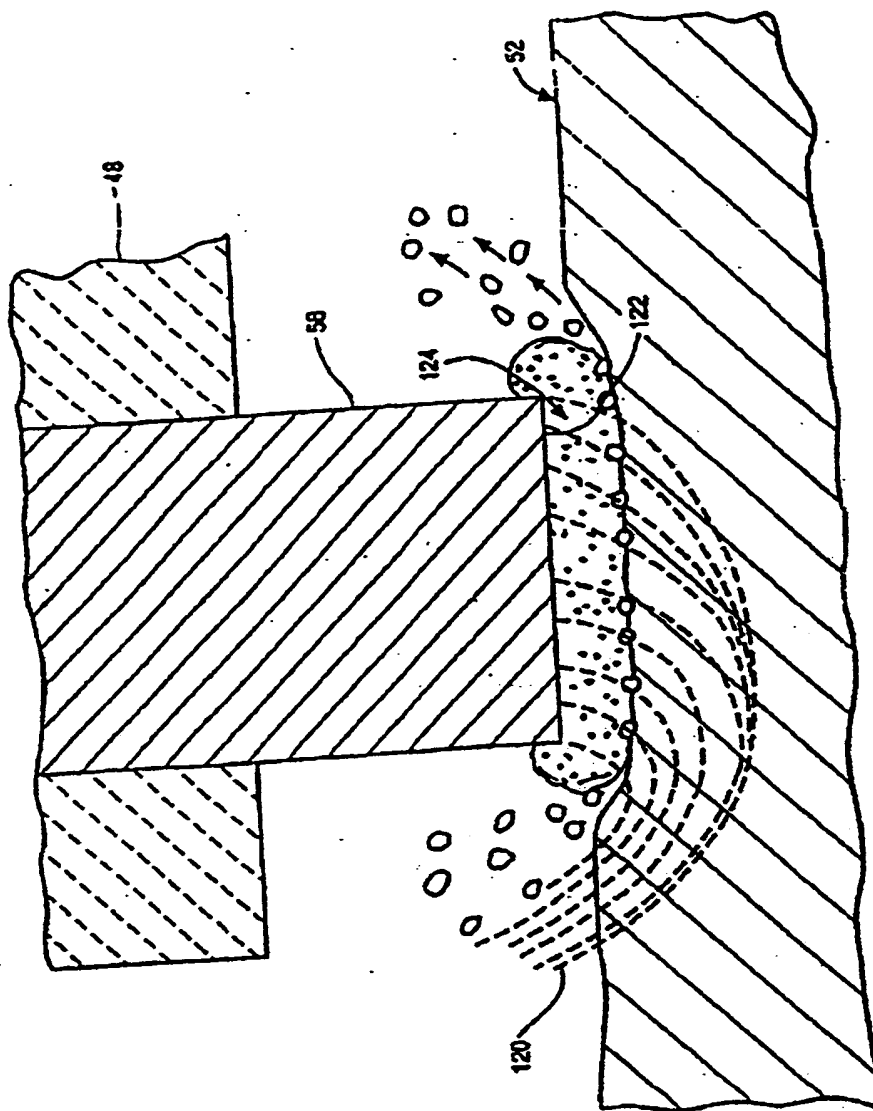
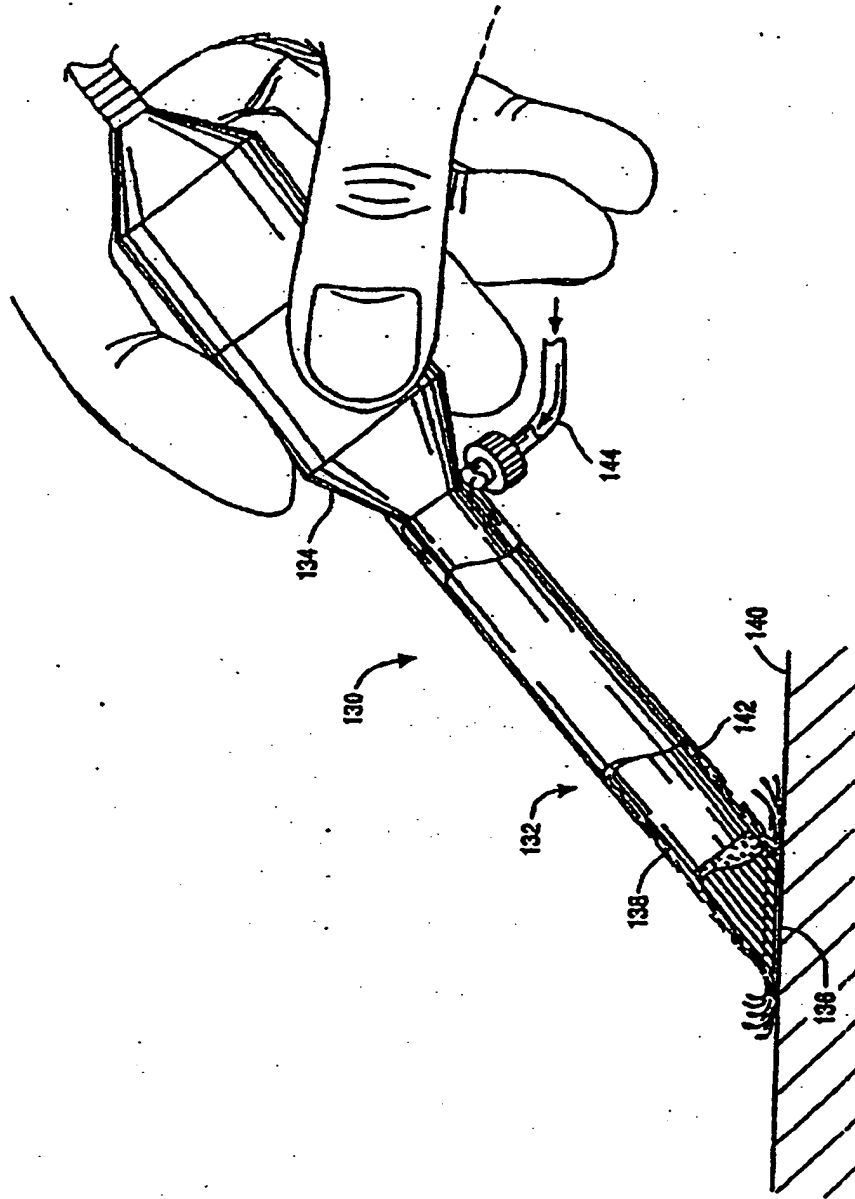


FIG. 16



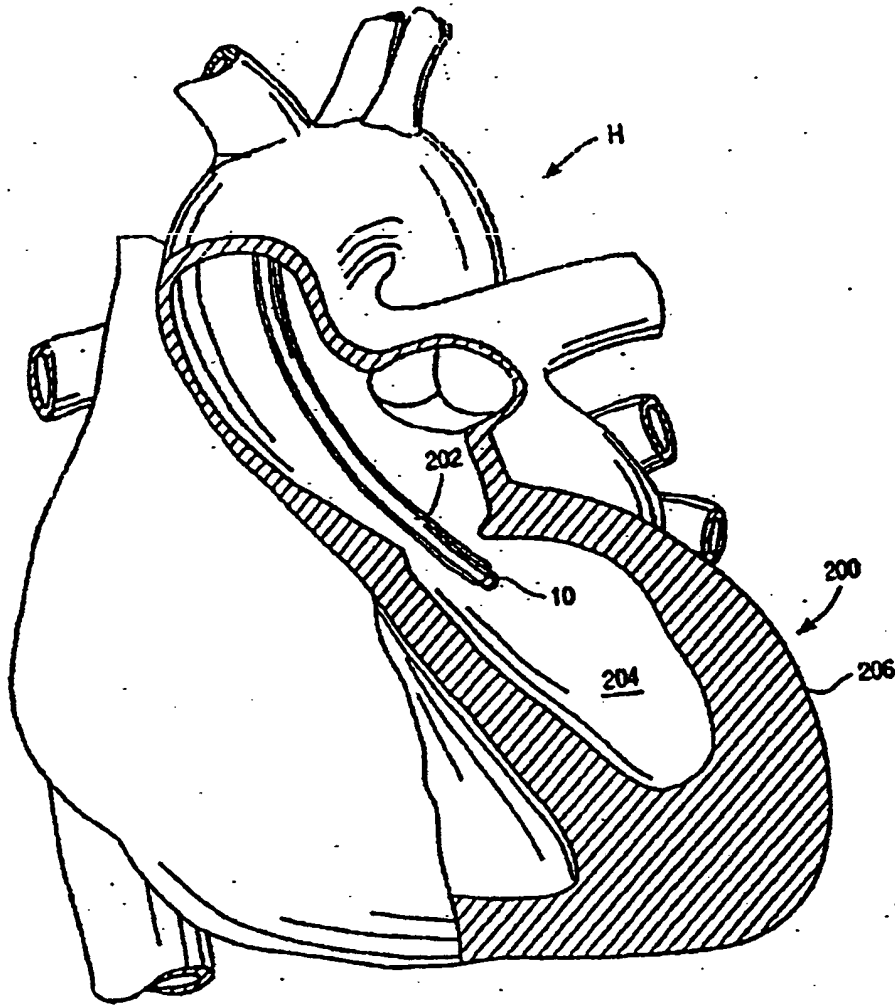


FIG. 18

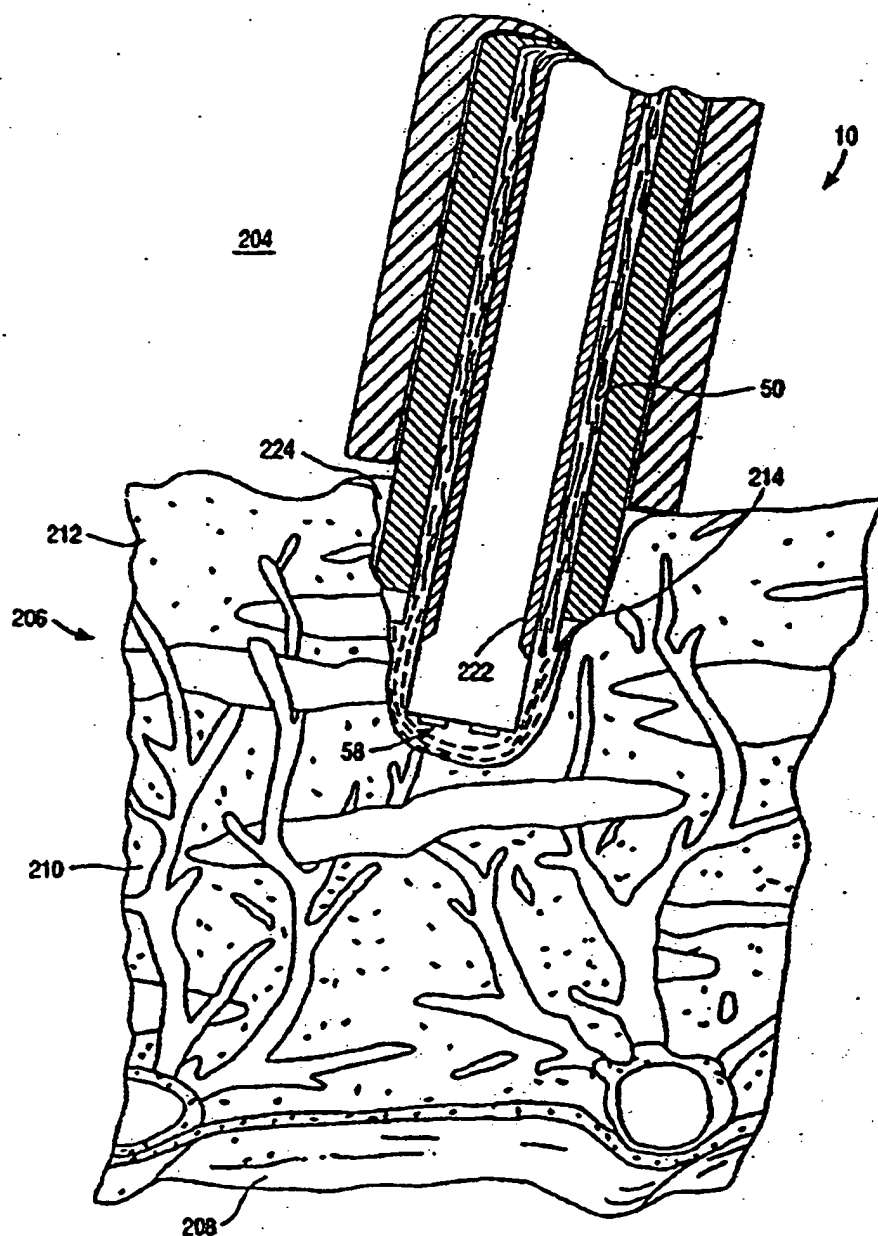


FIG. 19

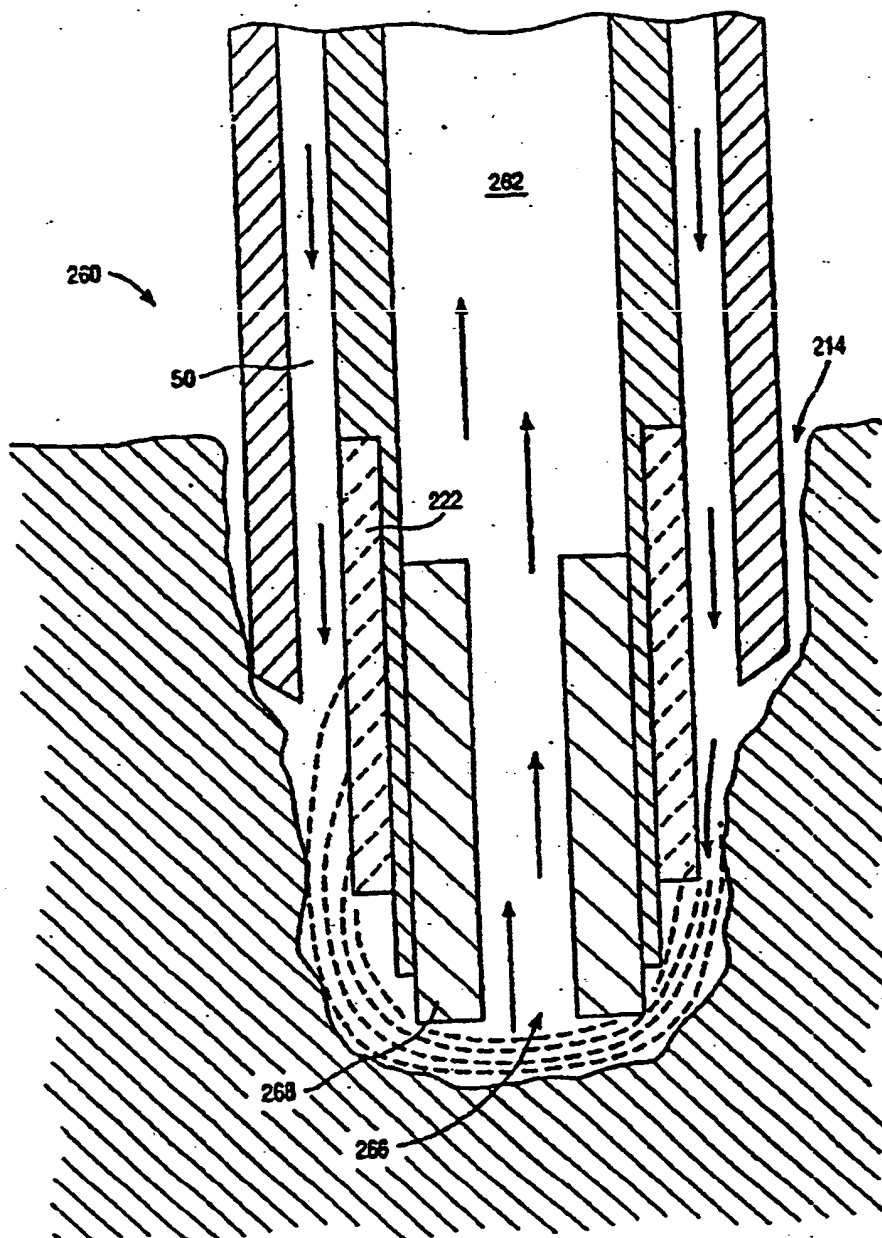


FIG. 20

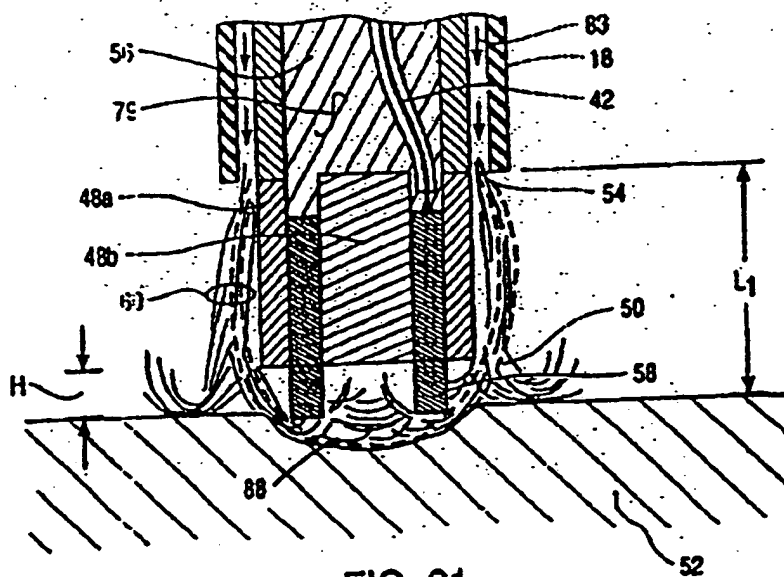


FIG. 21

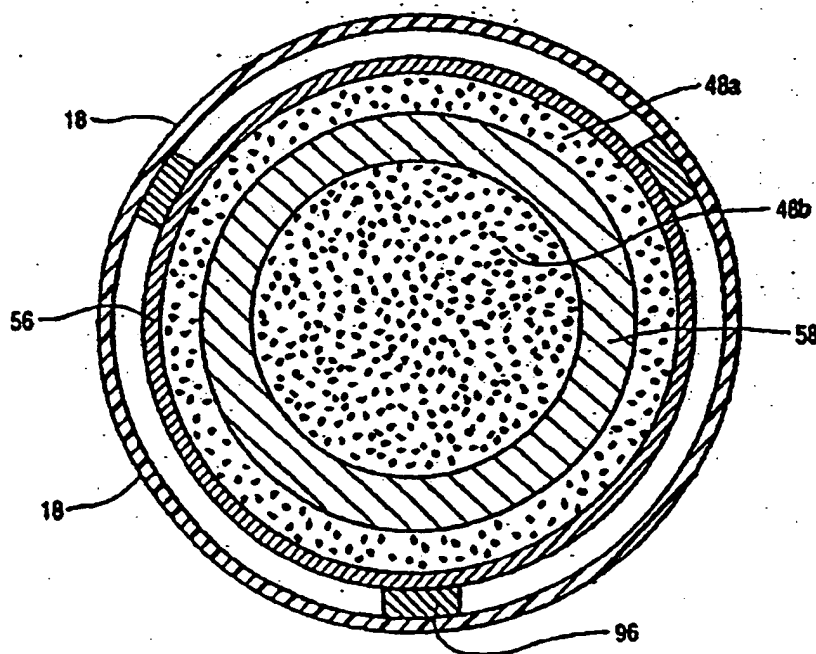


FIG. 22

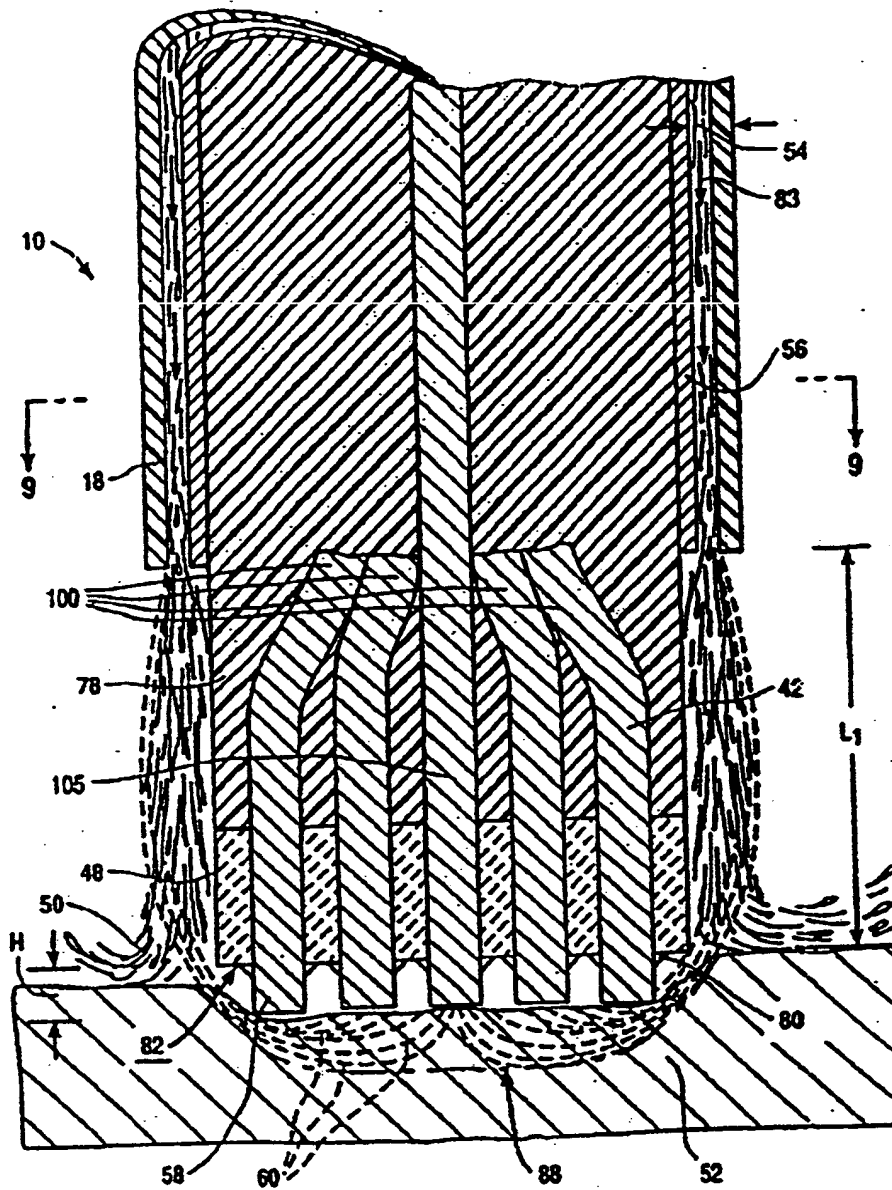


FIG. 23

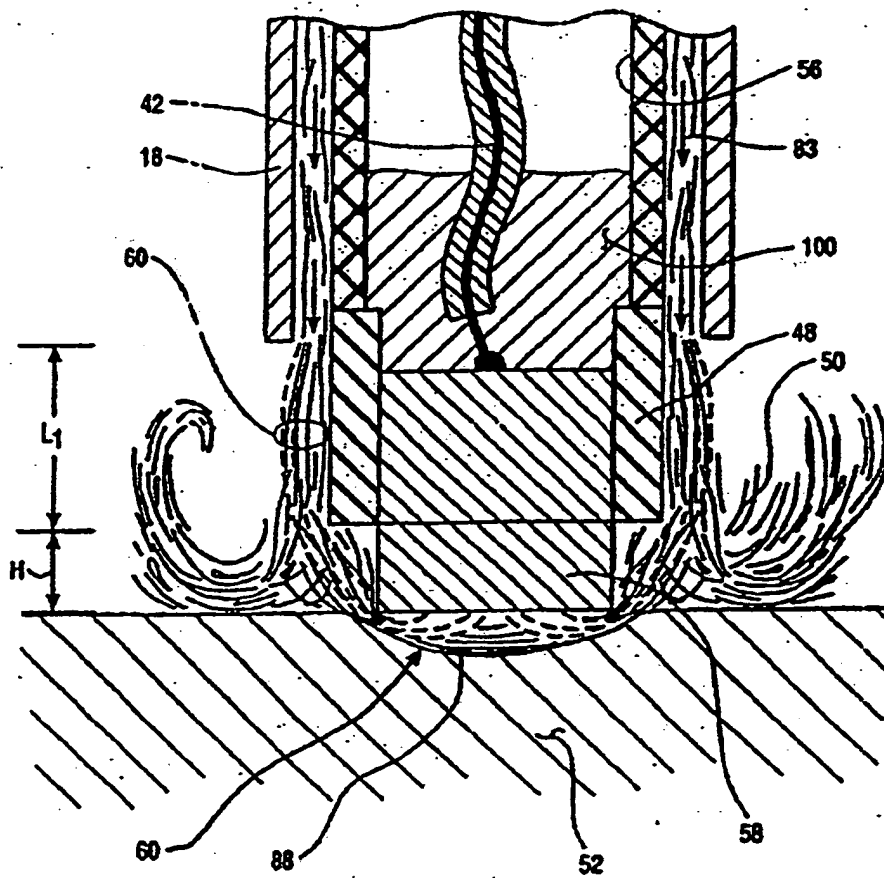


FIG. 24

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

The present invention is a continuation-in-part of application Ser. No. 08/483,219, filed on Jun. 7, 1995 and still pending, which was a continuation-in-part of PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993 and now abandoned, which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992 now U.S. Pat. No. 5,366,443, which was a continuation-in-part of application Ser. No. 07/817,573, filed on Jan. 7, 1992 now abandoned, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point

with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of tonsils or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for abating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as carbon lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric ablation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO₂ lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of

3 tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracoscopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent to the treatment site.

DESCRIPTION OF THE BACKGROUND ART

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1945) *J. Arthro. Surg.* 1:242-246 and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,455; 5,423,803; 5,102,410; 5,282,797; 5,290,273; 5,304,170; 5,312,395; 5,336,217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316; 4,658,817; 5,389,096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as scar or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity

4 to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the target tissue by a suitable distance during the ablation process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the

active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigant flooded environments, such as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return electrode.

The active and return electrodes will preferably be configured such that, upon the application of a sufficient high-frequency voltage, a thin layer of the electrically conducting liquid is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of ionizable species within the vapor layer or region and the emission of photons and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy

flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy flux.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmyocardial revascularization procedure;

FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmural channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for cannulizing or boring channels or holes through tissue, such as the ventricular wall during transmural revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the cannulization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance

characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently adjustable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electro-surgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electro-surgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable atoms and molecules, such as hydrogen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target

tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The photon energy produces photoablation through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photoablation is a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric breakdowns of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces areas which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or region into the tissue, thereby minimizing joulean heating in, and associated necrosis of, the tissue.

As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 10^{20} atoms/cm³, which corresponds to about 3×10^{-3} grams/cm³. Applicants also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 10^{20} atoms/cm³ for aqueous solutions), electron avalanche occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring in the region ahead of the front, viz. heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the induction of energetic electrons and photons. The electrical conductivity of the fluid (in units of millisiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to engage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes

13. having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and currents that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900 volts.

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art, the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to invariably affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. This power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 nH to 50,000 nH, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

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from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

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a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating therein.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 54 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 84 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-8, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through liquid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it beads radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 74 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of return electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 104a, 104b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 104a and 104b as indicated by current flux lines 60 to heat the target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described above.

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or arc tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48a of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloys thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 100. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or clamp connection 100. In FIG. 24, an electrosurgical probe 10

comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photons and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensable gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentations, such as freckles, tattoos, age or liver spots, birth marks, malignant melanomas, and superficial lentiginos in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodysplasia, e.g., skin angioma, malignant tumor tissue, humpage (i.e., tissue bulges extending from the vertebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an electro-surgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum lucidum and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmyocardial revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen enriched blood flowing into the ventricular cavity from the aorta to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electro-surgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electro-surgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 206, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

Electrically conducting liquid 50 is delivered through an annular lumen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58, preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiments, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 50 to flow over the tissue surface being cauterized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 20 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 240 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an open distal end 264 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 264 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, the heartbeat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole) of the heart.

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and positioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional manners. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficiently ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

What is claimed is:

1. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

2. The method of claim 1 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

3. The method of claim 2 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm².

4. The method of claim 2 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².

5. The method of claim 2 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0 mm.

6. The method of claim 2 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.

7. The method of claim 2 wherein the electrode terminals comprises a material with a relatively low thermal conductivity.

8. The method of claim 7 wherein the electrode materials comprises a material selected from the group consisting of titanium, tungsten, platinum, aluminum and tantalum.

9. The method of claim 2 wherein the return electrode has a distal end positioned proximal to the electrode array.

10. The method of claim 2 wherein the electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

11. The method of claim 2 wherein the electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

12. The method of claim 11 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

14. The method of claim 1 wherein at least a portion of the energy is in the form of energetic electrons.

15. The method of claim 14 wherein the energy of the energetic electrons is sufficient to cause disassociation or disintegration of molecules of the body structure.

16. The method of claim 14 wherein the energy evolved by the energetic electrons is greater than 3 eV.

17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.

18. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

19. The method of claim 1 wherein the electrode terminal is positioned between 0.02 to 5 mm from the target site.

20. The method of claim 1 wherein the vapor layer has a thickness of about 0.02 to 2.0 mm.

21. The method of claim 1 wherein the distance between the most proximal portion of the electrode terminal and the most distal portion of the return electrode is in the range from 0.5 to 10 mm.

22. The method of claim 1 wherein the electrode terminal and the return electrode are of comparable size and comprise a bipolar array of isolated electrode terminals which both come in close proximity or in contact with the body structure.

23. The method of claim 1 wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 2 mS/cm.

24. The method of claim 1 wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.

25. The method of claim 1 wherein the electrode height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

26. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being in the range from 500 to 1400 volts peak to peak.

27. The method of claim 26 wherein the high frequency voltage is in the range from 700 to 900 volts peak to peak.

28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

29. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal; and inducing the discharge of photons to the target site in contact with the vapor layer.

30. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the active electrode surface; and

inducing the discharge of energetic electrons to the target site in contact with the vapor layer.

31. The method of claim 28 wherein the depth of necrosis is 0 to 400 microns.

32. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that cause the breakdown of tissue through molecular dissociation or disintegration.

33. The method of claim 32 wherein the generating step comprises:

providing a return electrode electrically coupled to a high frequency voltage source;

applying a high frequency voltage between the electrode terminal and the return electrode; and

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal.

34. The method of claim 33 further comprising developing a film layer of vapor between the active electrode and the body structure at the target site.

35. The method of claim 33 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

36. The method of claim 35 wherein the cooling step includes translating the distal surface of the electrode terminal over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

37. The method of claims 1 and 28 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

38. The method of claim 37 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

39. The method of claim 37 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.

40. The method of claim 37 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.

41. The method of claims 28 and 32 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

42. The method of claim 41 wherein the generating step comprises:

providing a return electrode electrically coupled to a higher frequency voltage source;

applying a high frequency voltage between the return electrode and the array of electrode terminals; and

vaporizing the electrically conducting fluid in a thin layer over one or more of the electrode terminals of the array.

43. The method of claim 42 further comprising developing a film layer of vapor between one or more of the electrode terminals and the target site.

44. The method of claim 42 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

45. The method of claims 1 and 33 wherein the density of the vapor layer is less than about 10^{20} atoms/cm³.

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46. The method of claims 1 and 39 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 1 and 28 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

48. The method of claims 26 and 28 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 26 and 28 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

50. The method of claims 26 and 28 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.

51. The method of claims 26 and 28 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

52. The method of claims 1 and 28 further comprising cooling the tissue with the electrically conducting fluid to

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reduce the temperature rise of those portions of the body structure adjacent the target site.

53. The method of claim 52 wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

55. The method of claims 1 and 28 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 26 and 28 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

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(54) **SYSTEMS AND METHODS FOR
ELECTROSURGICAL TISSUE TREATMENT
IN CONDUCTIVE FLUID**

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**This patent is subject to a terminal dis-
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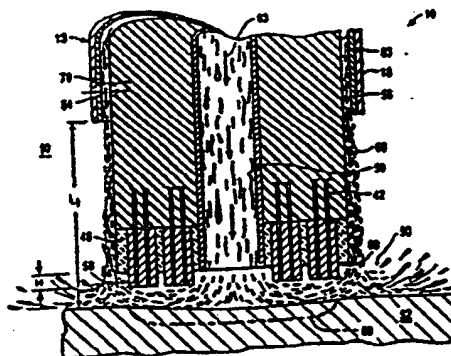
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(57) **ABSTRACT**

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (58) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the return electrode and the electrode array so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the active and return electrodes.

43 Claims, 17 Drawing Sheets



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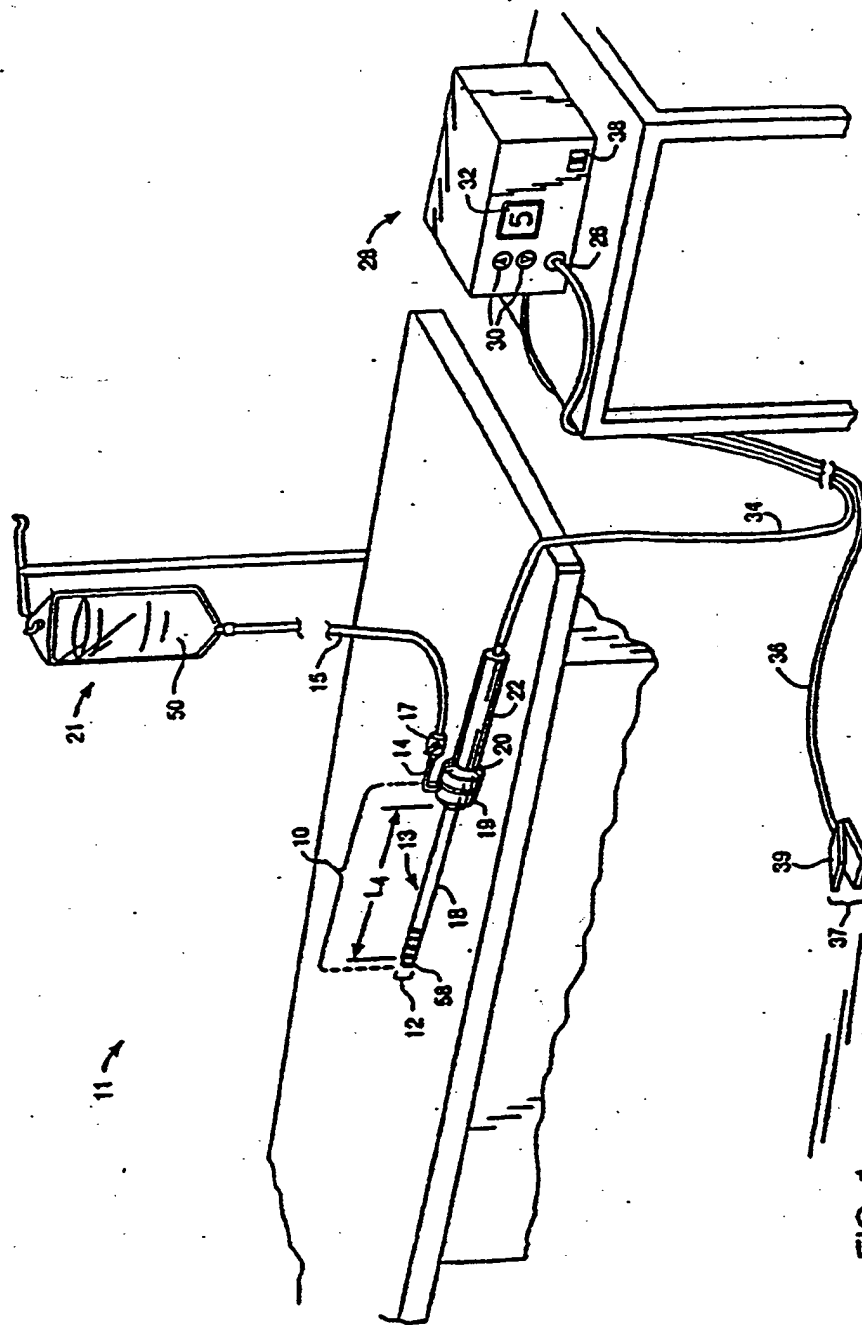
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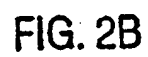
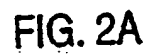
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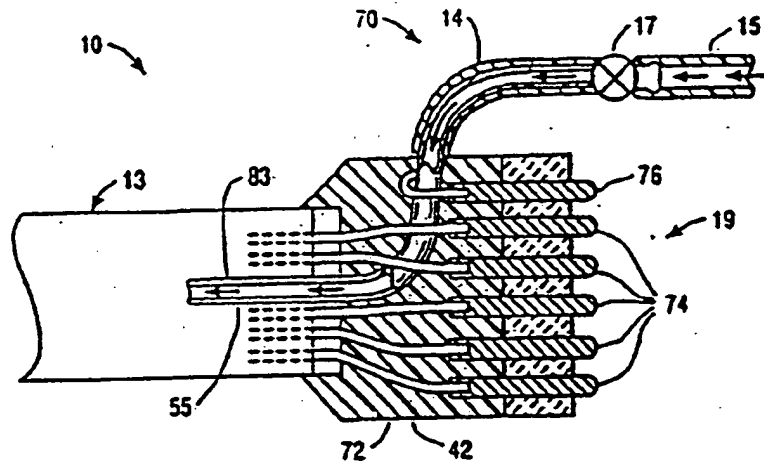


FIG. 2C

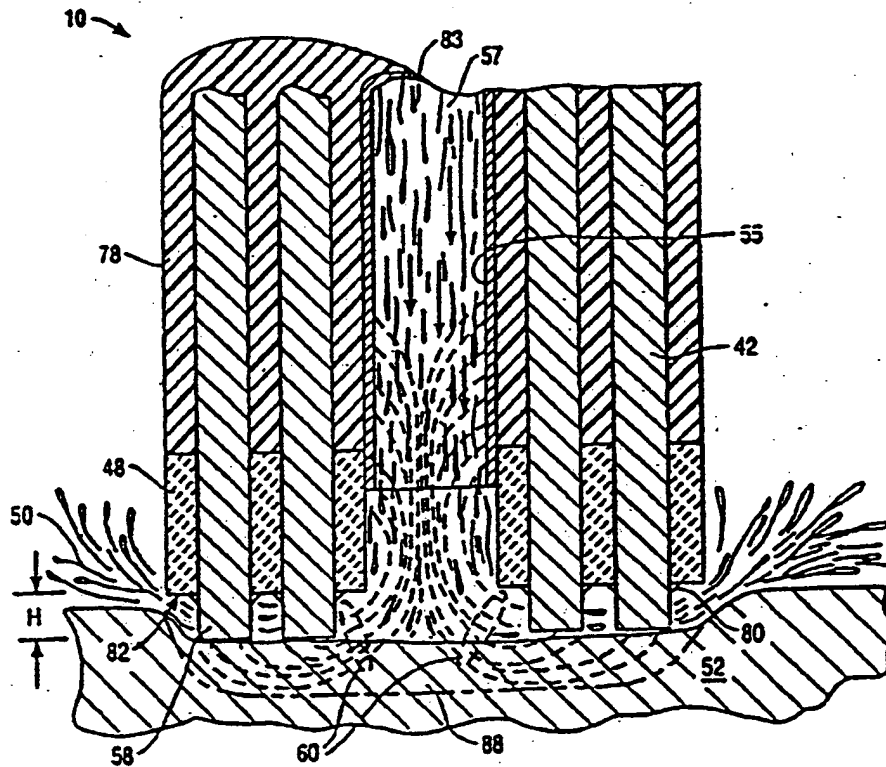


FIG. 3

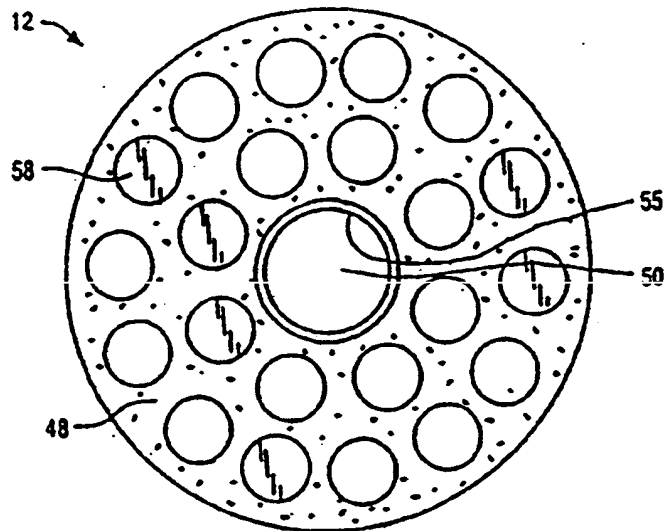


FIG. 4

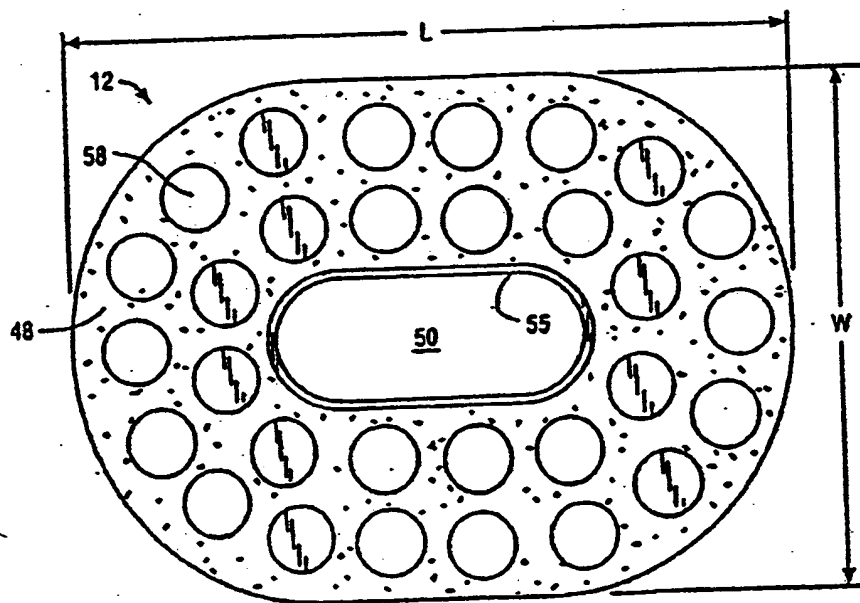


FIG. 5

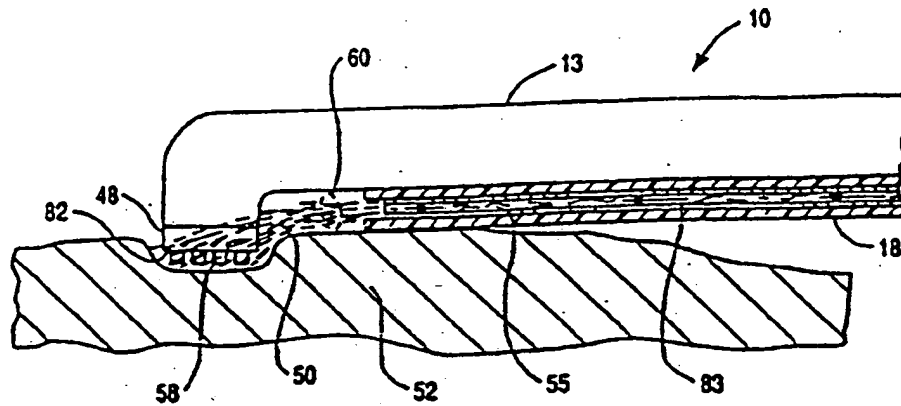


FIG. 6

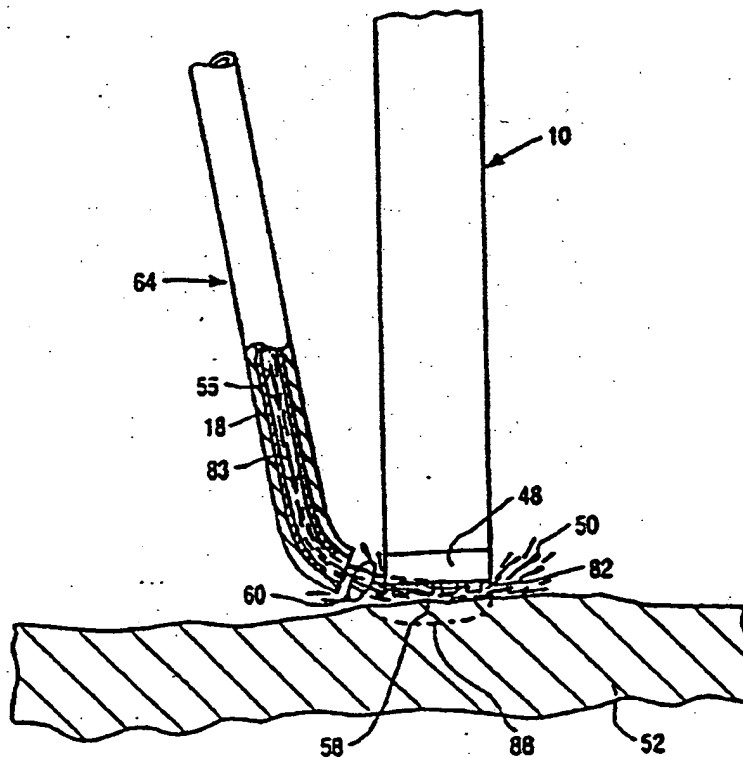


FIG. 7

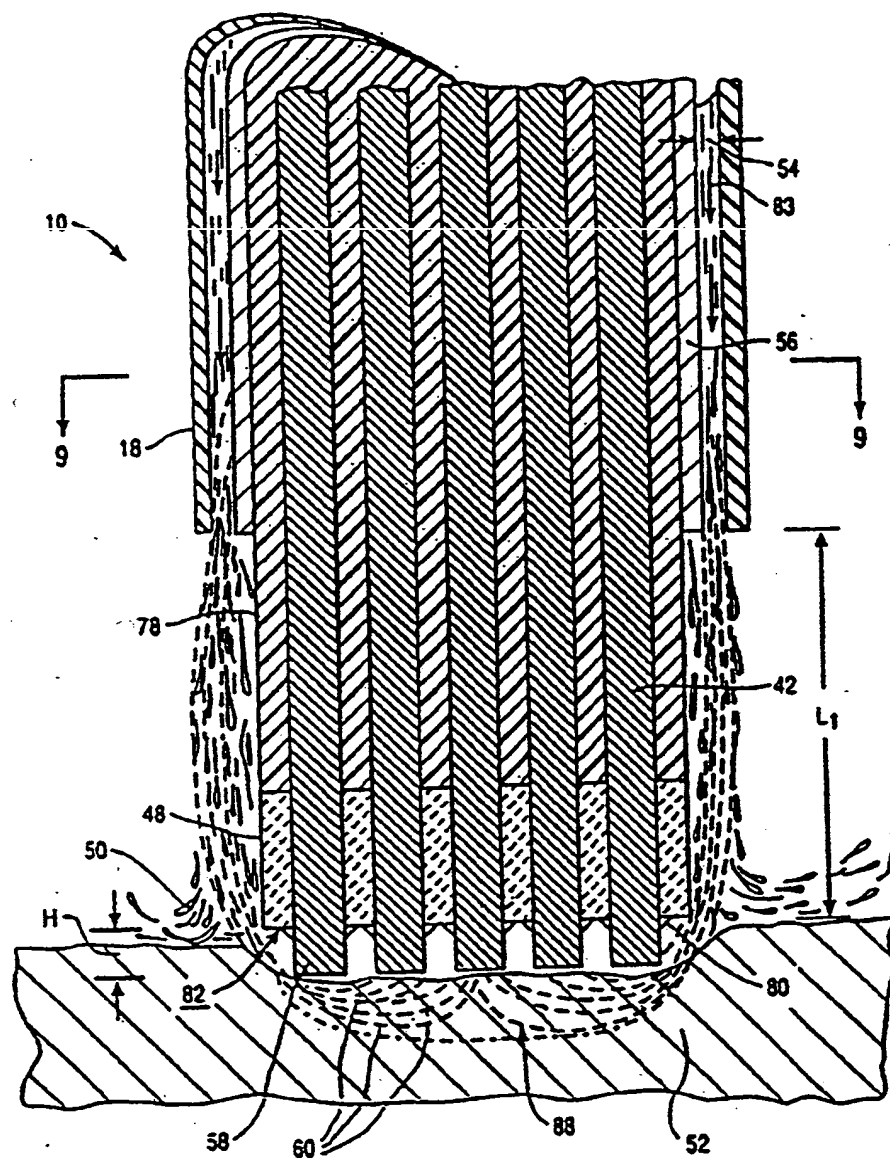


FIG. 8

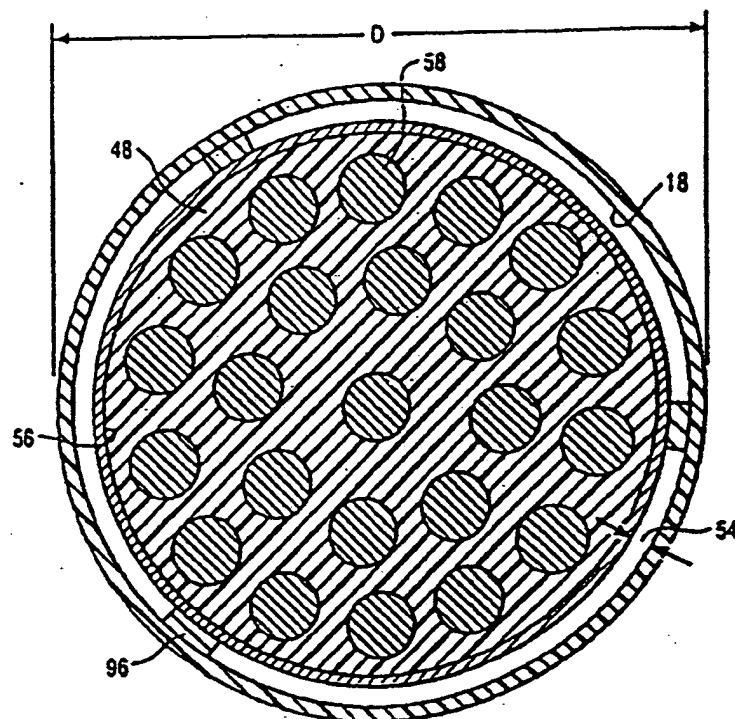


FIG. 9

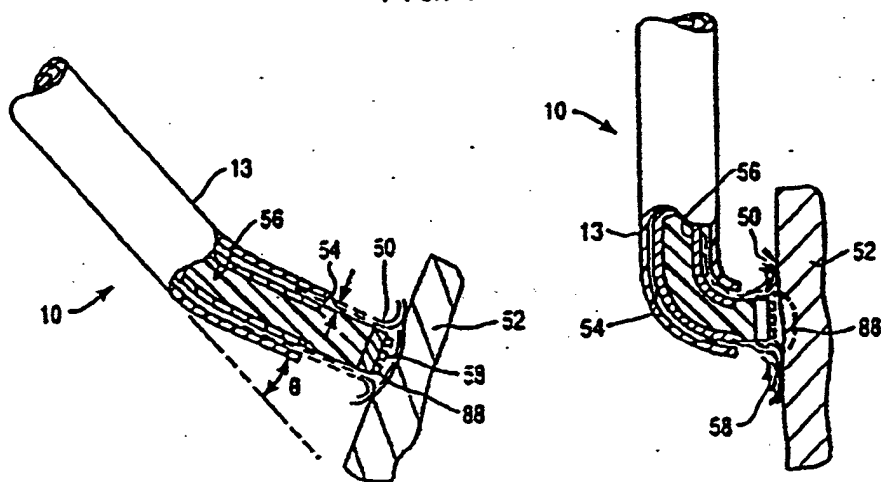


FIG. 10

FIG. 11

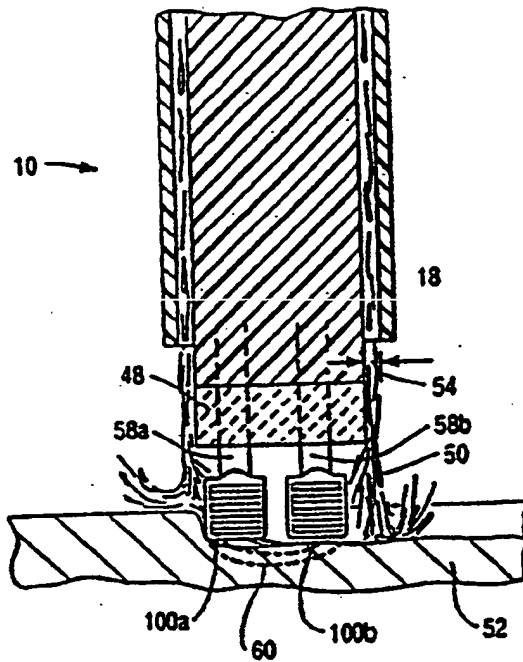


FIG. 12

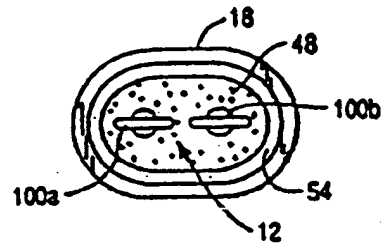


FIG. 13

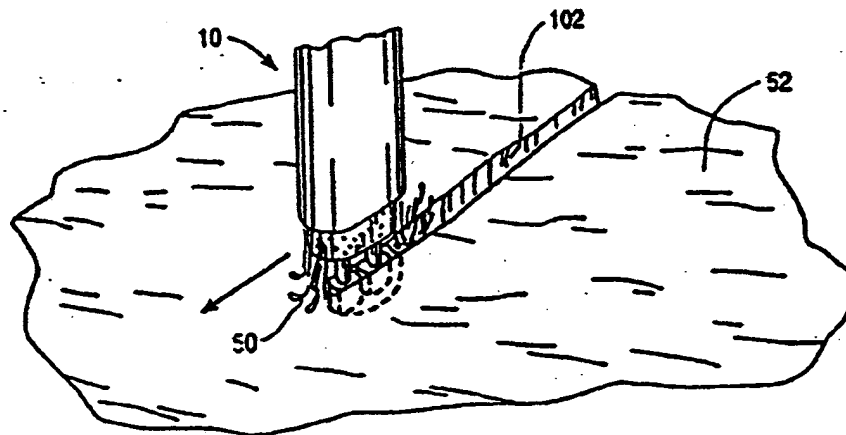


FIG. 14

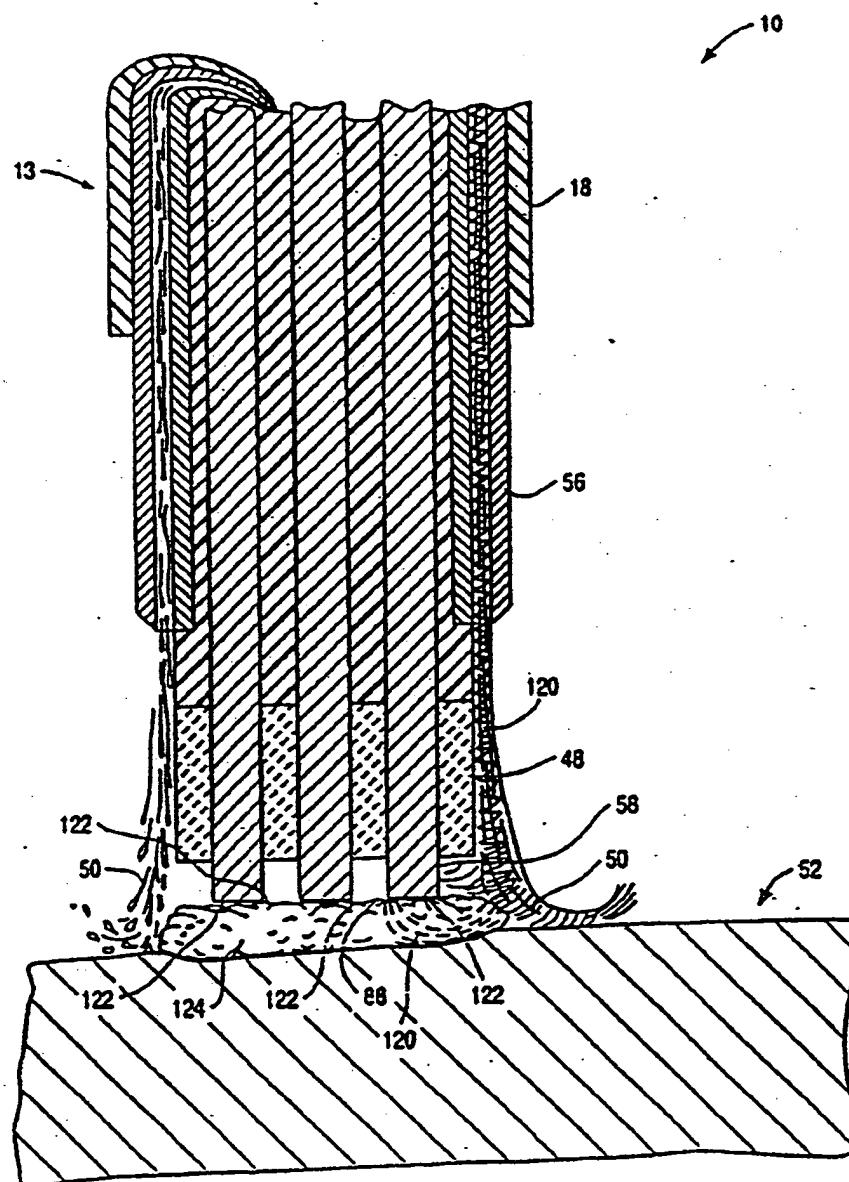


FIG. 15

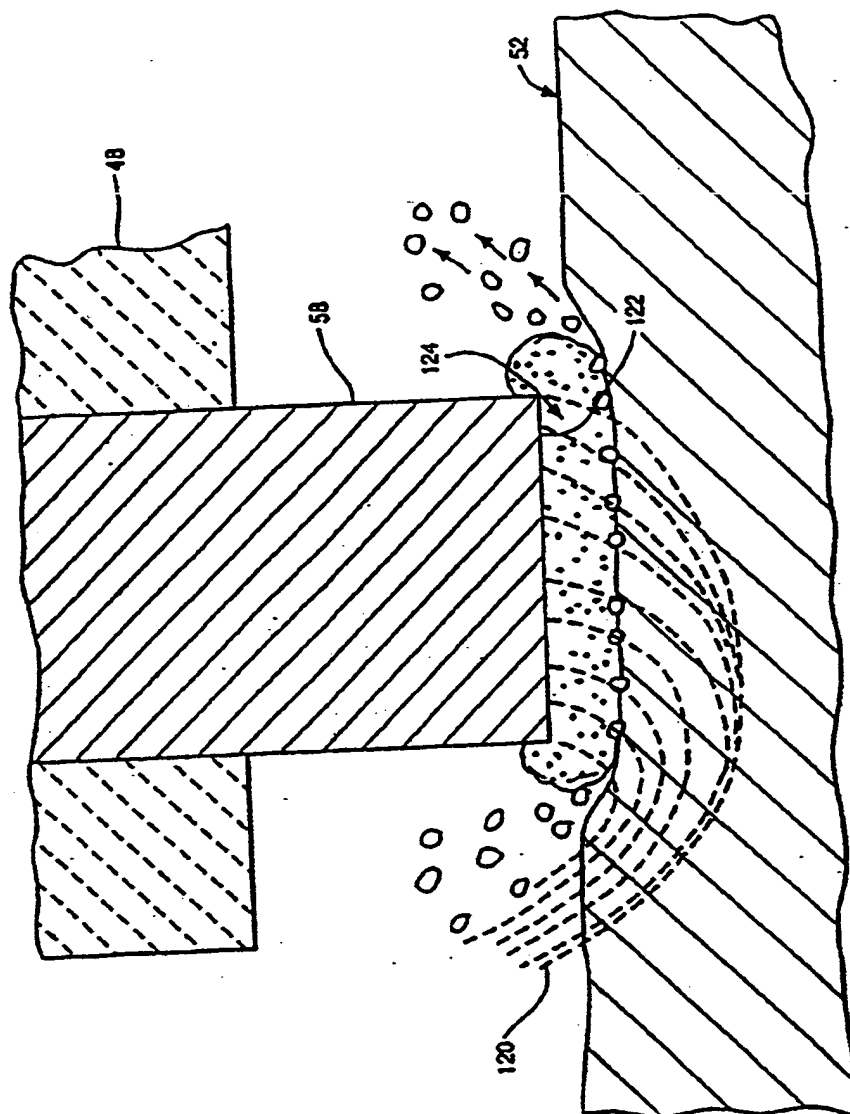
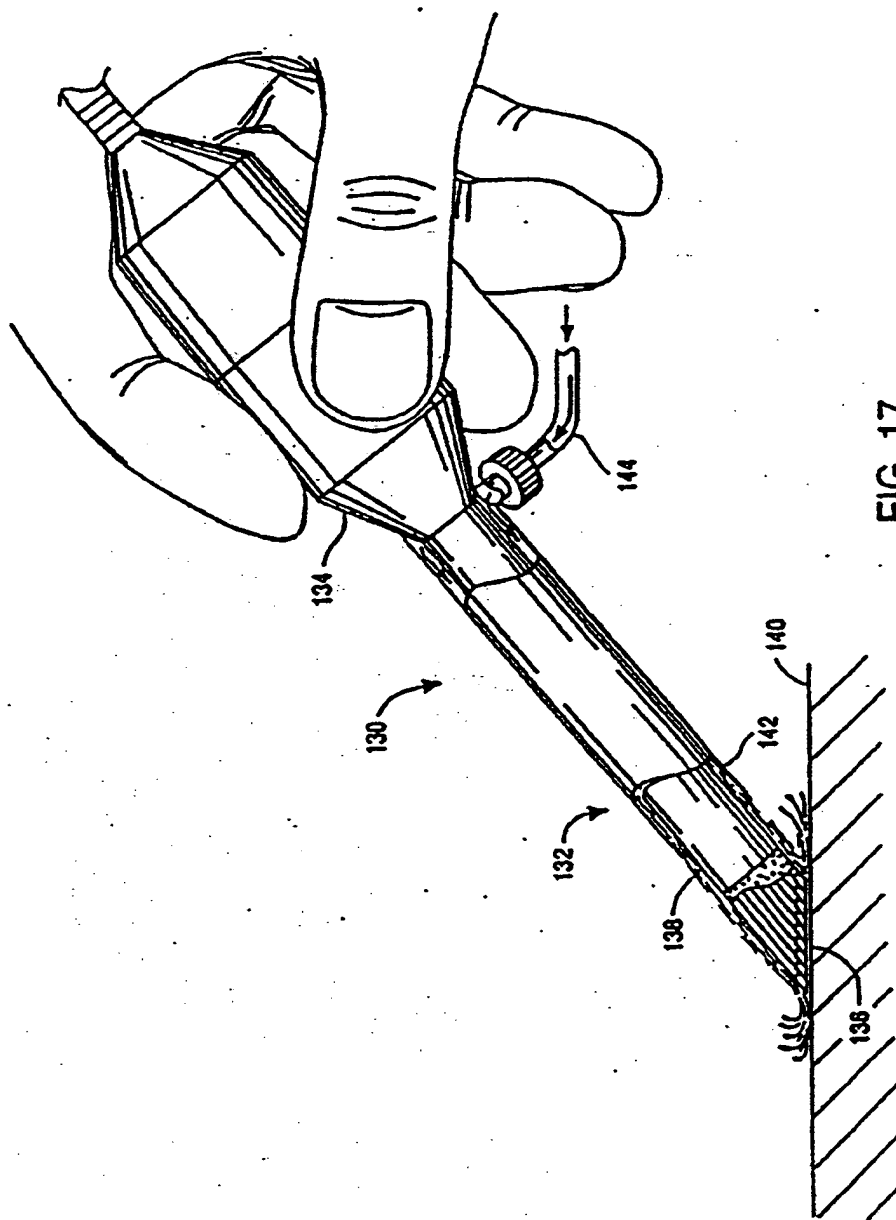


FIG. 16



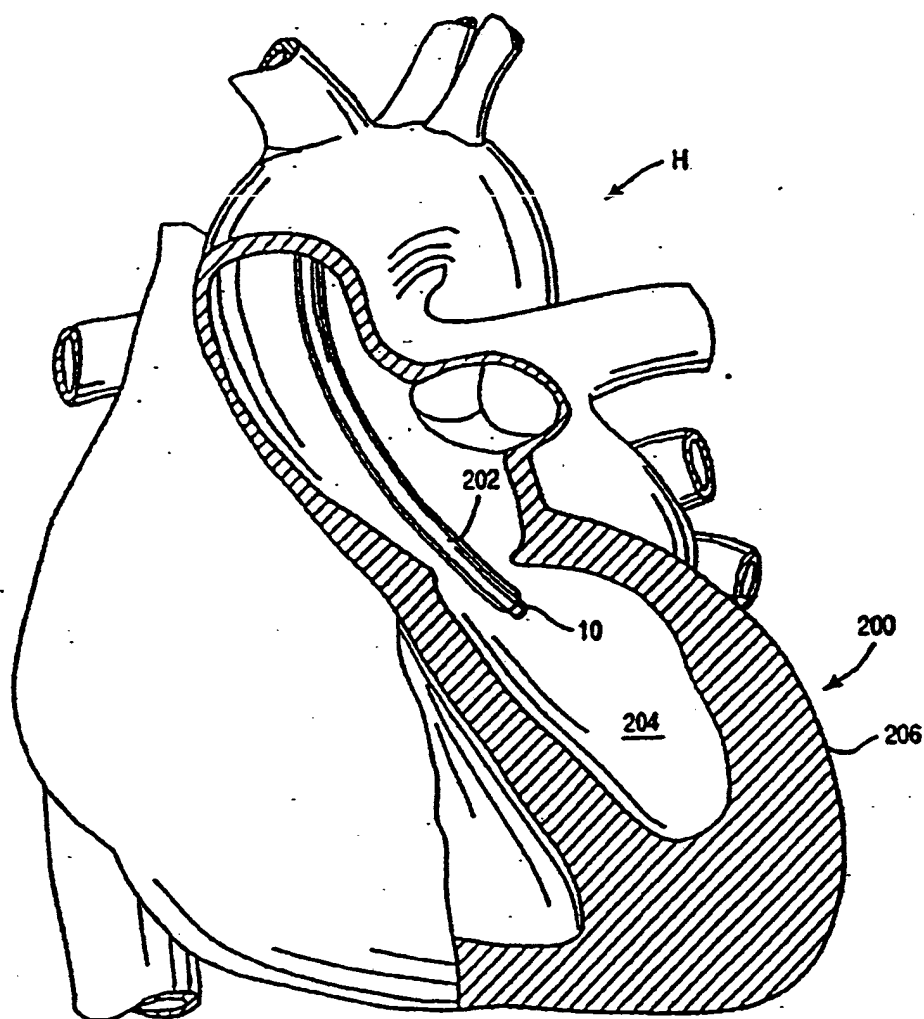


FIG. 18

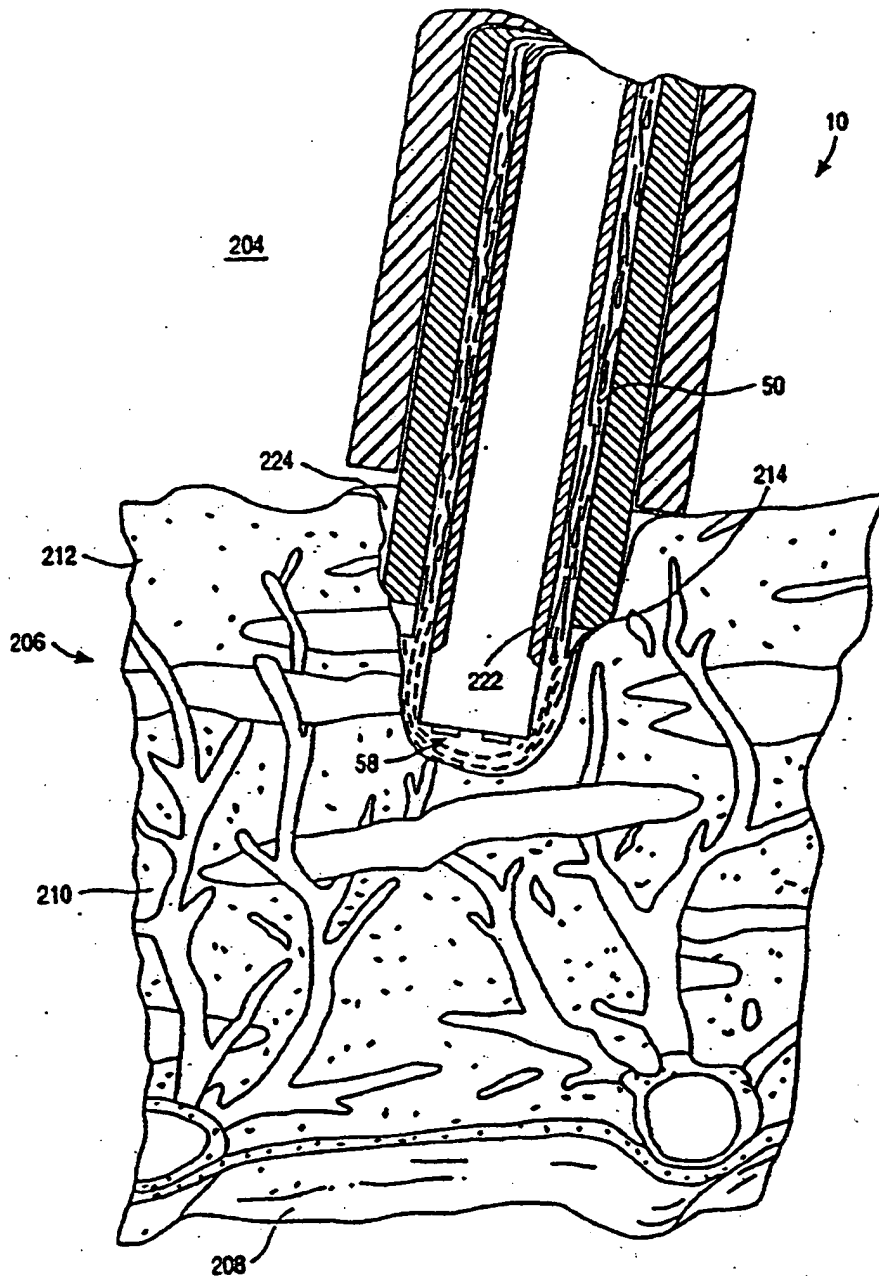


FIG. 19

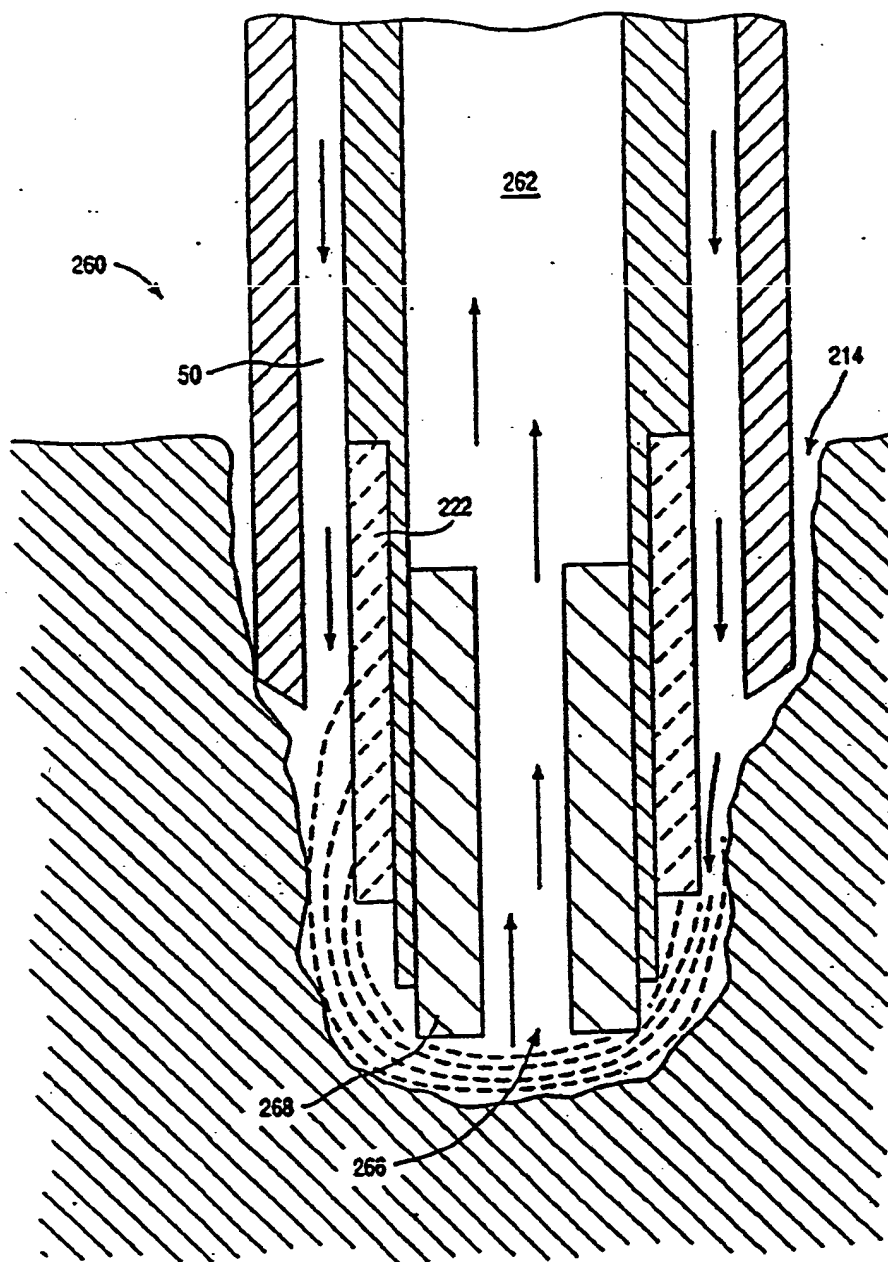


FIG. 20

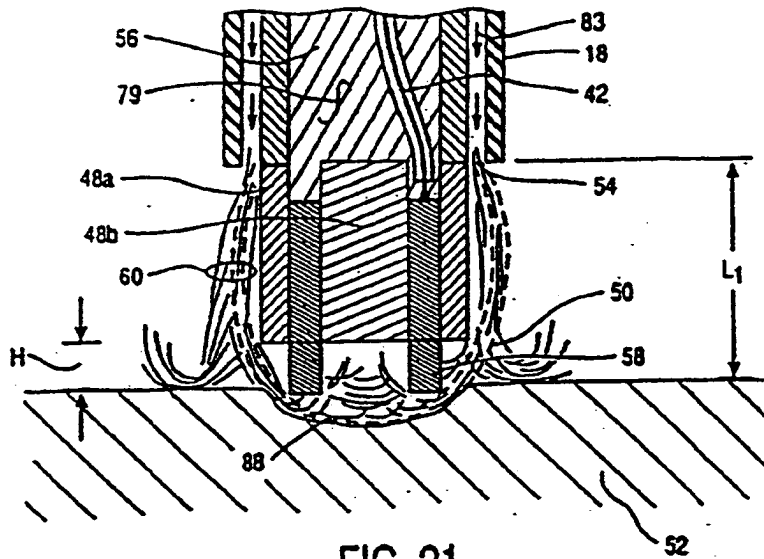


FIG. 21

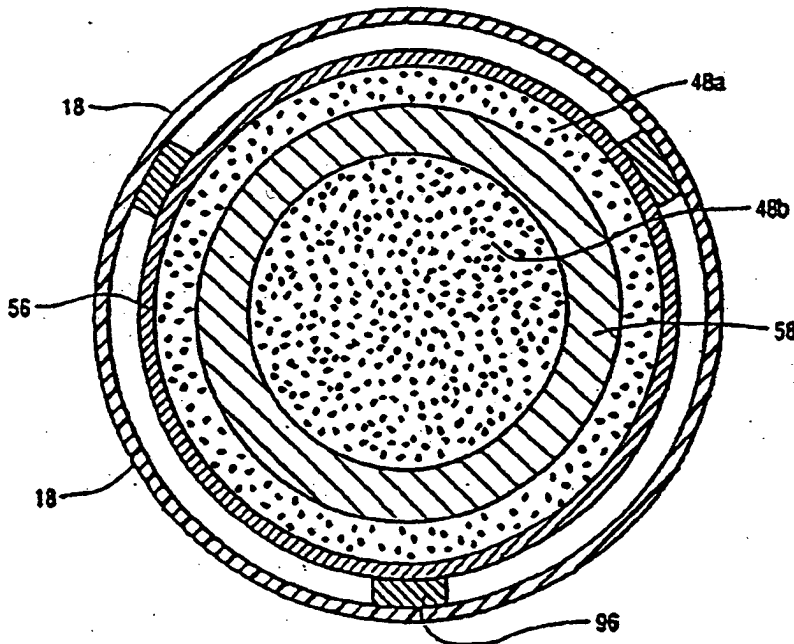


FIG. 22

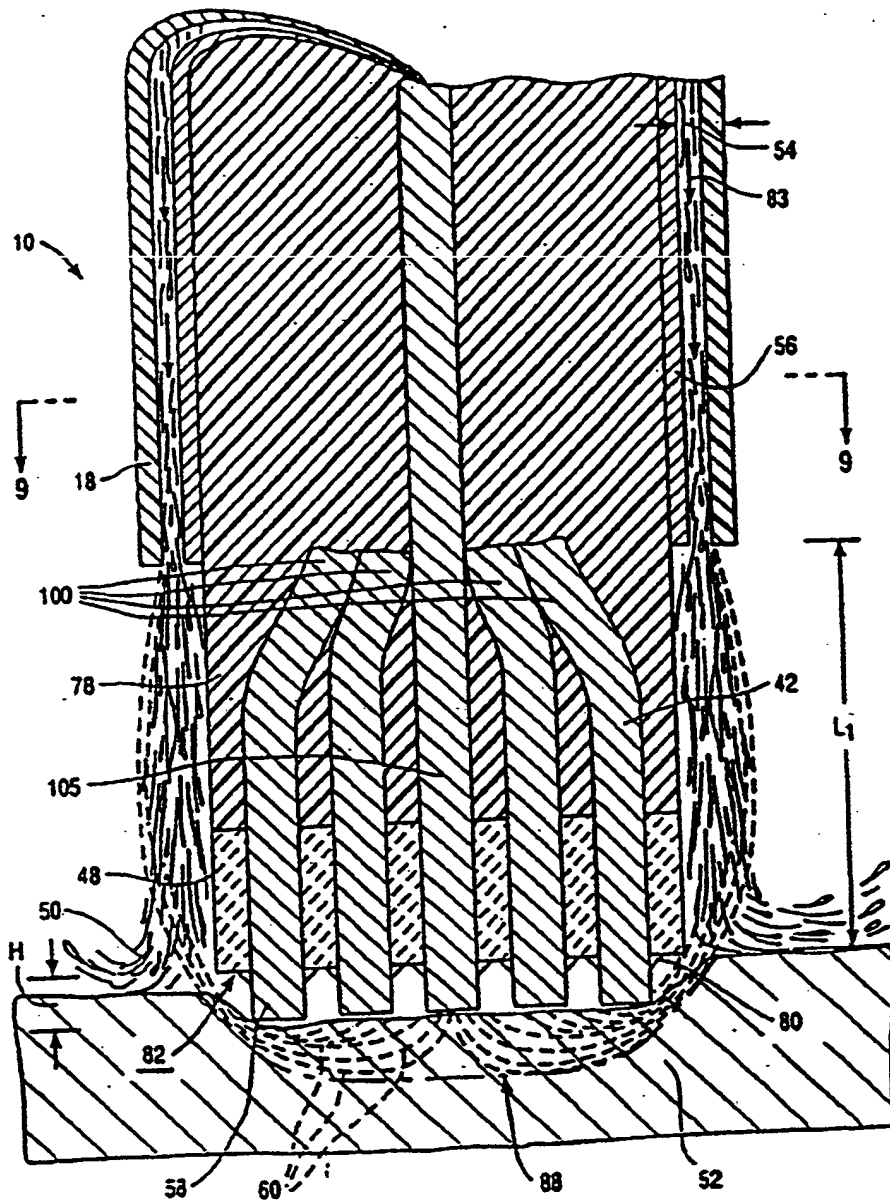


FIG. 23

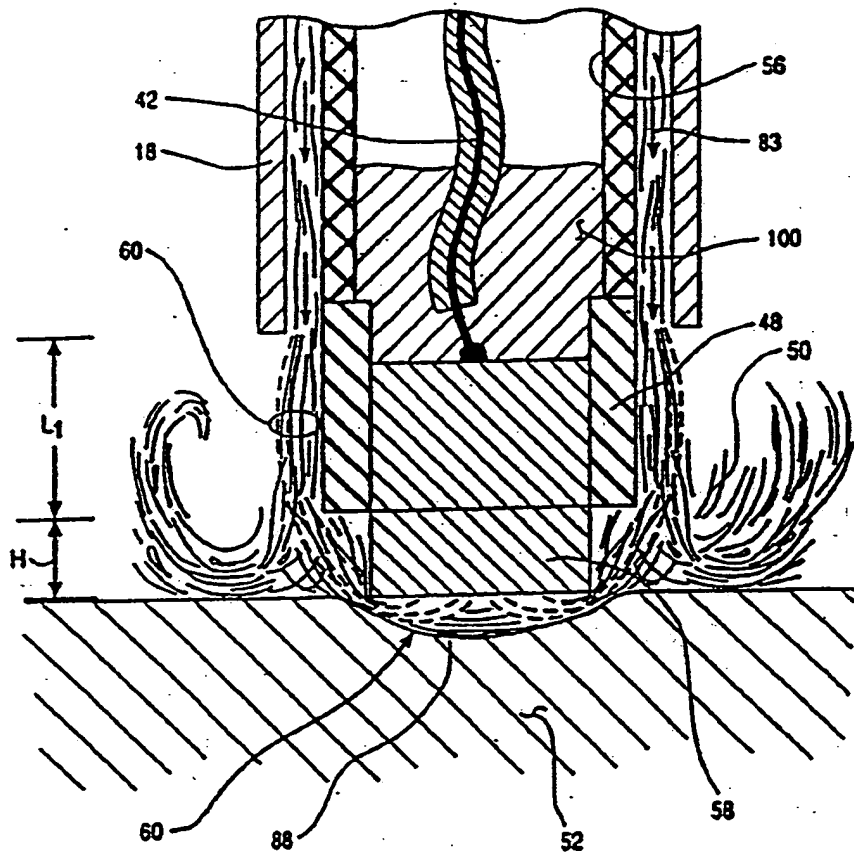


FIG. 24

SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE TREATMENT IN CONDUCTIVE FLUID

The present invention is a division of application Ser. No. 08/795,686, filed Feb. 5, 1997, now U.S. Pat. No. 5,871,469, which is a division of application Ser. No. 08/561,958, filed Nov. 22, 1995, now U.S. Pat. No. 5,697,882, which is a continuation-in-part of application Ser. No. 08/485,219, filed Jun. 7, 1995, now U.S. Pat. No. 5,697,281, which is a continuation-in-part of application Ser. No. 08/446,767 filed Jun. 2, 1995, now U.S. Pat. No. 5,697,909 which is a U.S. National Phase Filing of International Application No. PCT/US94/05169, filed May 10, 1994, which is a continuation-in-part of application Ser. No. 08/059,681, filed May 10, 1993, now abandoned, which is a continuation-in-part of application Ser. No. 07/958,977, filed Oct. 9, 1992, now U.S. Pat. No. 5,366,443, which is a continuation-in-part of application Ser. No. 07/817,575, filed Jan. 7, 1992, now abandoned, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically

exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as eximer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric ablation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO_2

lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracoscopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent to the treatment site.

2. Description of the Background Art

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1:242-246 and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while coagulated, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,455, 5,423,803, 5,102,410, 5,282,797, 5,290,273, 5,304,170, 5,312,395, 5,336,217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316, 4,658,817, 5,389,096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as scar or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the target tissue by a suitable distance during the ablation

process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigant flooded environments, such as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return electrode.

The active and return electrodes will preferably be configured such that, upon the application of a sufficient high-frequency voltage, a thin layer of the electrically conducting liquid is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of ionizable species within the vapor layer or region and the emission of photon and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with

or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy flux.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmyocardial revascularization procedure;

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FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmyocardial channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for canalizing or boring channels or holes through tissue, such as the ventricular wall during transmyocardial revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the canalization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Ser. No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by using isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

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The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance

characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electro-surgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltages differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from vapor layer and to the surface of the target tissue. This energy may be in the form of energetic photons

(e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The photon energy produces photobleaching through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photobleaching is a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric breakdown of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces areas which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or region into the tissue, thereby minimizing joulean heating in, and associated necrosis of, the tissue.

As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 10^{20} atoms/cm³, which corresponds to about 3×10^{-3} grams/cm³. Applicants also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 10^{20} atoms/cm³ for aqueous solutions), electron avalanche occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring the region ahead of the front, viz, heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the inducement of energetic electrons and photons. The electrical conductivity of the fluid (in units of millisiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to engage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes

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having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and current that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900 volts.

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed laser duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art, the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to irreversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

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hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 nH to 50,000 nH, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

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from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

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a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating therein.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 11 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-5, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described above.

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or arc tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48a of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloys thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 108. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or crimp connection 100. In FIG. 24, an electrosurgical probe 10

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comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photon and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensable gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentations, such as freckles, tanos, age or liver spots, birth marks, malignant melanomas, and superficial lentiginos in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodyplasia, e.g., skin anglioma, malignant tumor tissue, humpago (i.e., tissue bulges extending from the vernebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an electrosurgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

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delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum lucidum and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmural revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen enriched blood flowing into the ventricular cavity from the aorta to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electrosurgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electrosurgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 204, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

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Electrically conducting liquid 50 is delivered through an annular lumen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58, preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiments, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 50 to flow over the tissue surface being canalized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 20 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 260 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an open distal end 266 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 266 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, the heartbeat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole) of the heart.

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and positioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional manners. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

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other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

What is claimed is:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:

positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;

positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and

applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

2. The method of claim 1 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

3. The method of claim 1 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.

4. The method of claim 1 further comprising delivering the electrically conductive fluid to the target site.

5. The method of claim 4 wherein the electrode terminal is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the electrode terminal.

6. The method of claim 5 wherein the return electrode is an outer tubular member defining an axial passage between the outer surface of the probe and the inner surface of the outer tubular member, the delivering step including directing the electrically conductive fluid through the axial passage to the distal end of the probe over the electrode terminal.

7. The method of claim 4 further including positioning a distal end of a fluid supply shaft adjacent the electrode terminal, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the electrode terminal.

8. The method of claim 4 wherein the electrode terminal is located on a distal end of a probe and the return electrode is an inner tubular member defining an axial lumen, the delivering step including directing electrically conductive fluid through the axial lumen to the distal end of the probe over the electrode terminal.

9. The method of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of an instrument shaft.

10. The method of claim 1 wherein the electrode terminal includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft.

11. The method of claim 1 wherein the electrically conductive fluid comprises isotonic saline.

12. The method of claim 1 including independently controlling current flow to the electrode terminal based on

electrical impedance between the electrode terminal and the return electrode.

13. The method of claim 1 wherein the return electrode is spaced from the electrode terminal such that when the electrode terminal is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the electrode terminal and the return electrode.

14. The method of claim 1, wherein the return electrode is located on a distal end of an instrument shaft, further comprising an insulating matrix on the instrument shaft between the return electrode and the electrode terminal, the insulating matrix comprising an inorganic material.

15. The method of claim 14 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

16. The method of claim 14 further comprising applying a sufficient voltage difference between the return electrode and the electrode terminal to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal.

17. The method of claim 1 further comprising measuring the temperature at the target site and limiting power delivery to the electrode terminal if the measured temperature exceeds a threshold value.

18. The method of claim 1 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

19. The method of claim 18 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

20. The method of claim 18 wherein at least a portion of the energy is in the form of energetic electrons.

21. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

22. The method of claim 1 further comprising generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:

contacting an active electrode with the body structure in the presence of an electrically conductive fluid;

spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and

applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.

24. The method of claim 23 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

25. The method of claim 23 wherein at least a portion of the electric current passes through the body structure.

26. The method of claim 23 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path between the active electrode and the return electrode.

27. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.

28. The method of claim 27 wherein the active electrode is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the active electrode.

29. The method of claim 27 further including positioning a distal end of a fluid supply shaft adjacent the active electrode, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the active electrode.

30. The method of claim 23 wherein the active electrode comprises a single active electrode disposed near the distal end of an instrument shaft.

31. The method of claim 23 wherein the active electrode includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft.

32. The method of claim 23 wherein the electrically conductive fluid comprises isotonic saline.

33. The method of claim 23 including independently controlling current flow to the active electrode based on electrical impedance between the active electrode and the return electrode.

34. The method of claim 23 wherein the return electrode is spaced from the active electrode such that when the active electrode is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the active electrode and the return electrode.

35. The method of claim 23, wherein the return electrode is located on a distal end of a probe, further comprising an insulating matrix at the distal tip of the probe between the return electrode and the active electrode, the insulating matrix comprising an inorganic material.

36. The method of claim 35 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

37. The method of claim 23 further comprising applying a sufficient voltage difference between the return electrode and the active electrode to effect the electrical breakdown of tissue in the immediate vicinity of the active electrode.

38. The method of claim 23 further comprising measuring the temperature at the target site and limiting power delivery to the active electrode if the measured temperature exceeds a threshold value.

39. The method of claim 23 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the active electrode and to induce the discharge of energy to the target site in contact with the vapor layer.

40. The method of claim 39 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

41. The method of claim 39 wherein at least a portion of the energy is in the form of energetic electrons.

42. The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

43. The method of claim 23 further comprising generating a voltage gradient between the active electrode and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.



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Eggers et al.

(10) Patent No.: **US 6,224,592 B1**
(45) Date of Patent: ***May 1, 2001**

(54) **SYSTEMS AND METHODS FOR
ELECTROSURGICAL TISSUE TREATMENT
IN CONDUCTIVE FLUID**

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(*) Notice: Subject to any disclaimer, the term of this
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(62) Division of application No. 08/795,686, filed on Feb. 5,
1997, now Pat. No. 5,871,469, which is a division of
application No. 08/561,958, filed on Nov. 22, 1995, now Pat.
No. 5,697,882, which is a continuation-in-part of application
No. 08/485,219, filed on Jun. 7, 1995, now Pat. No. 5,697,
281, which is a continuation-in-part of application No.
08/446,767, filed as application No. PCT/US94/05168 on
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No. 5,366,443, which is a continuation-in-part of application
No. 07/817,575, filed on Jan. 7, 1992, now abandoned.

(51) Int. Cl.⁷ A61B 18/12; A61B 18/14

(52) U.S. Cl. 606/32; 606/41; 606/46;
604/114; 607/99; 607/105; 607/113

(58) Field of Search 606/32, 41, 46,
606/49, 50, 34; 607/98, 99, 101, 105, 113;
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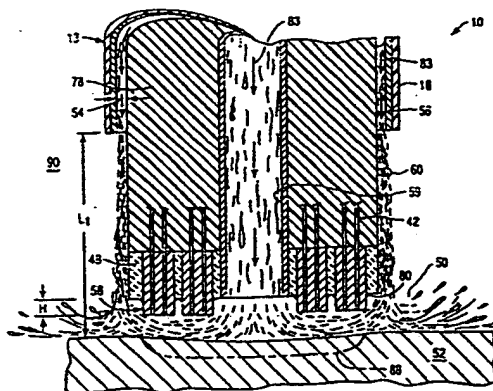
(74) Attorney, Agent, or Firm—John T. Raffle.

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ABSTRACT

An electrosurgical probe (10) comprises a shaft (13) having
an electrode array (58) at its distal end and a connector (19)
at its proximal end for coupling the electrode array to a high
frequency power supply (28). The shaft includes a return
electrode (56) recessed from its distal end and enclosed
within an insulating jacket (18). The return electrode defines
an inner passage (83) electrically connected to both the
return electrode and the electrode array for passage of an
electrically conducting liquid (50). By applying high fre-
quency voltage to the electrode array and the return
electrode, the electrically conducting liquid generates a
current flow path between the return electrode and the
electrode array so that target tissue may be cut or ablated.
The probe is particularly useful in dry environments, such as
the mouth or abdominal cavity, because the electrically
conducting liquid provides the necessary return current path
between the active and return electrodes.

43 Claims, 17 Drawing Sheets



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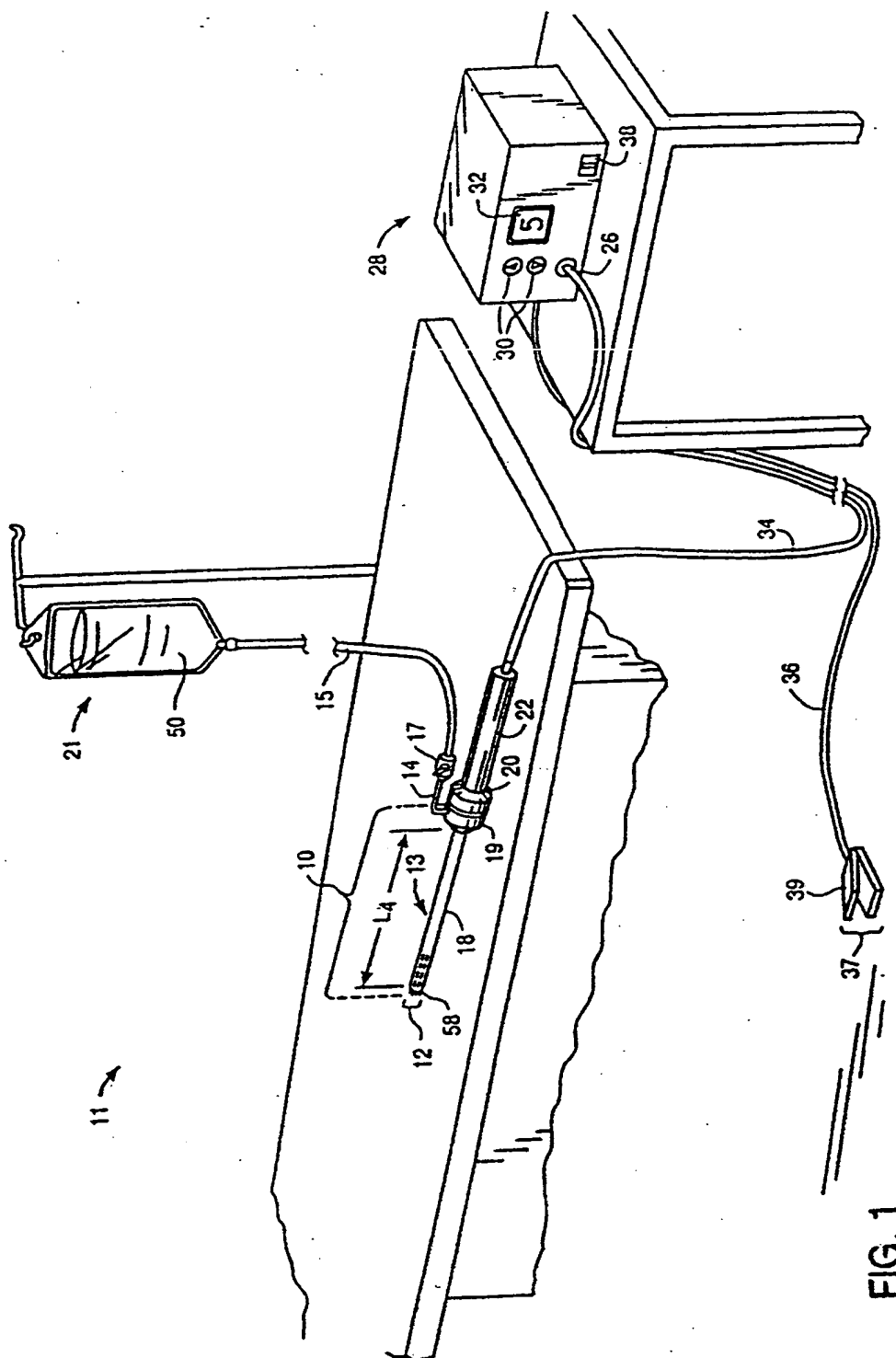
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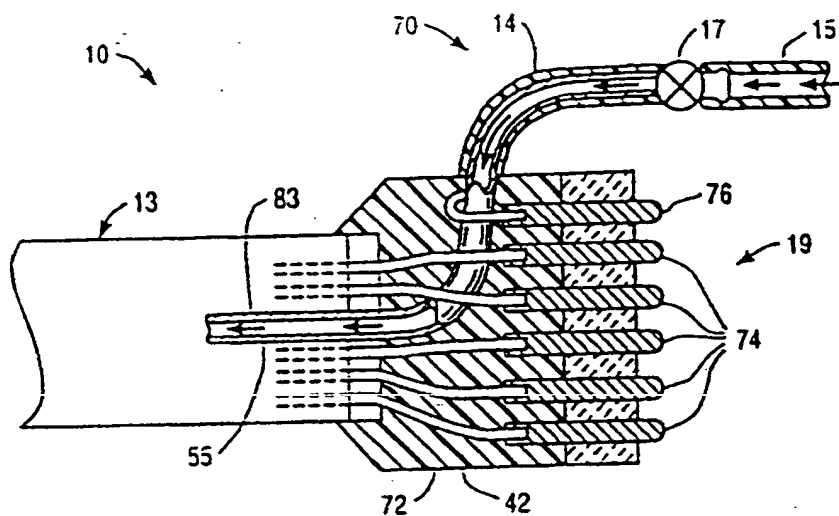


FIG. 2C

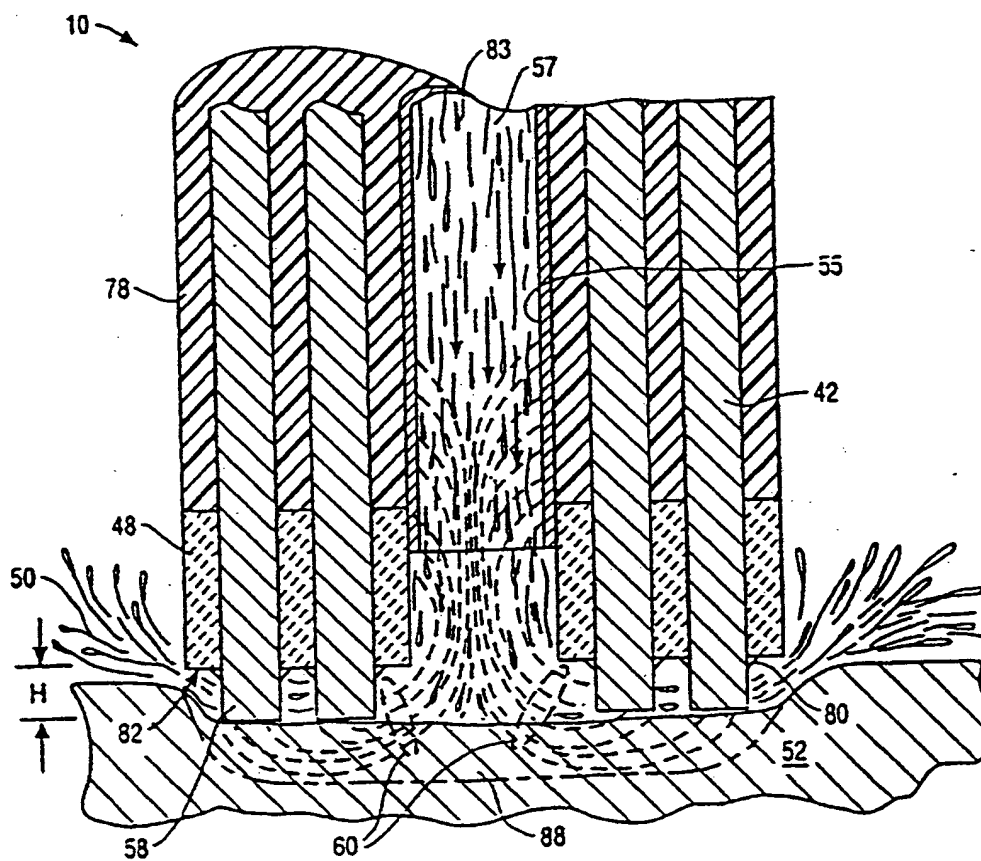


FIG. 3

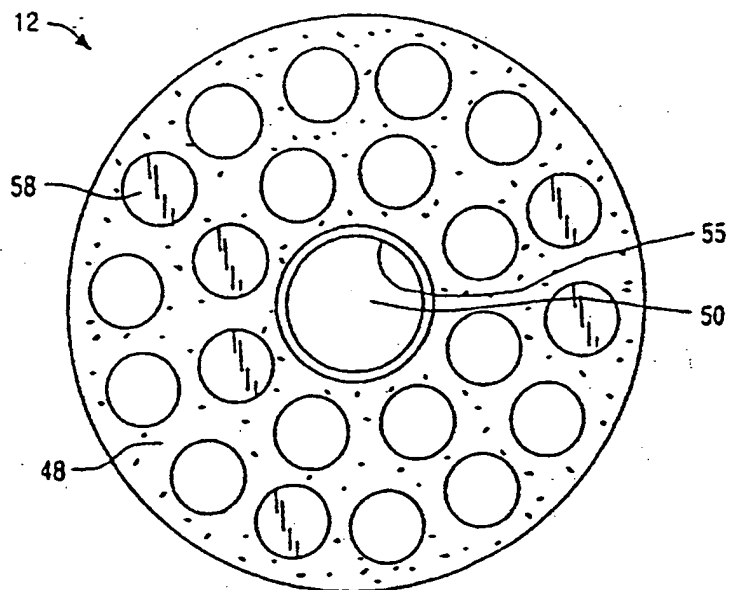


FIG. 4

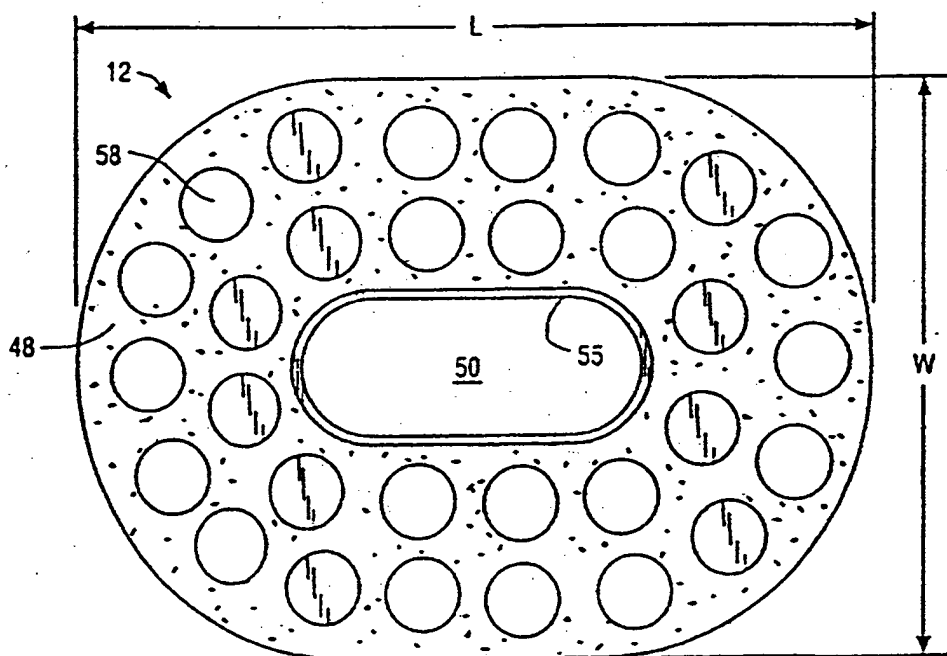


FIG. 5

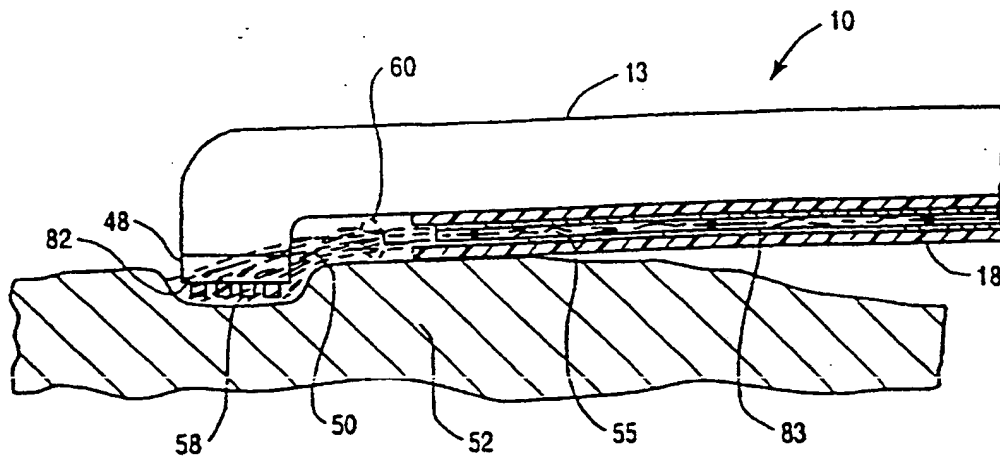


FIG. 6

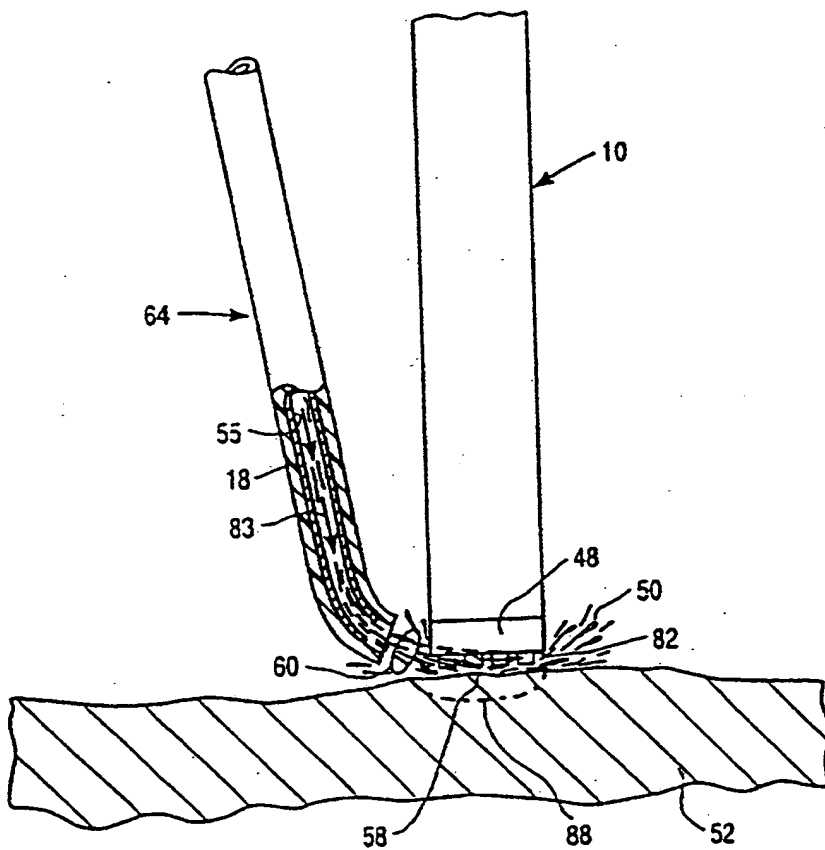


FIG. 7

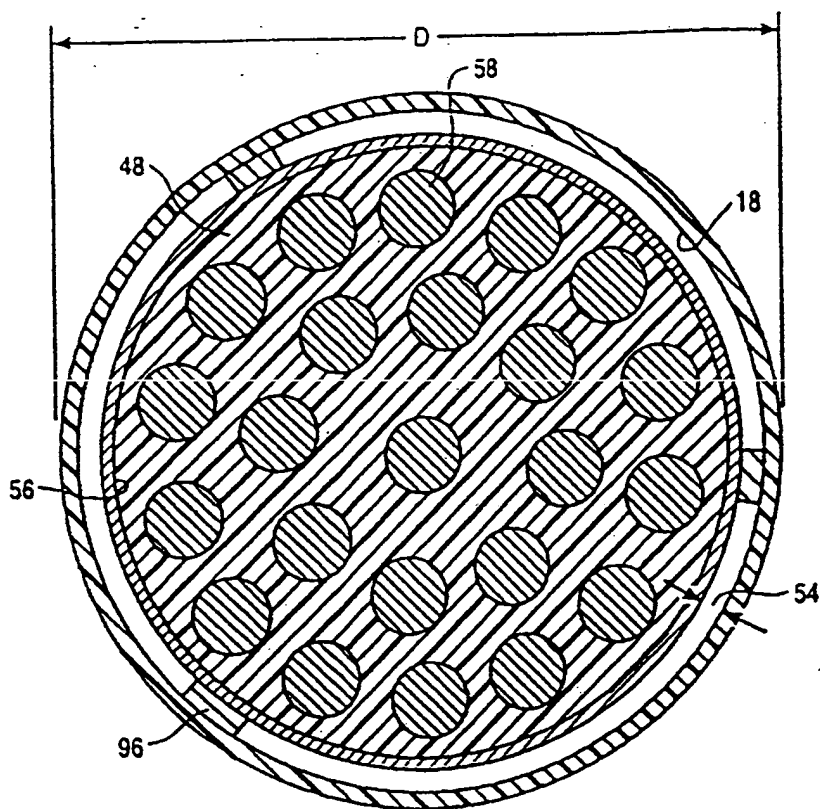


FIG. 9

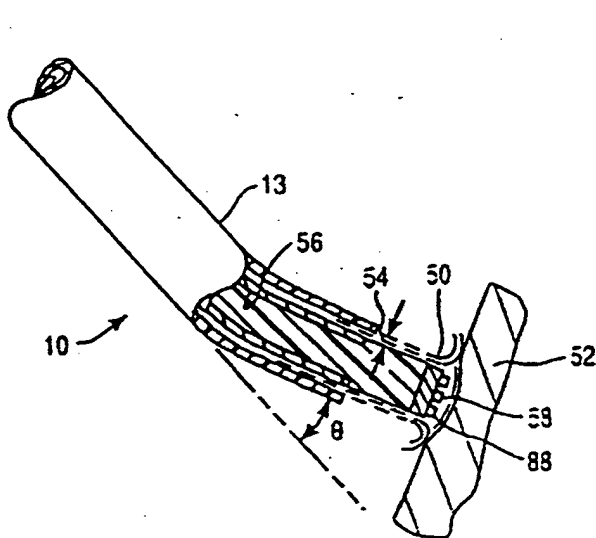


FIG. 10

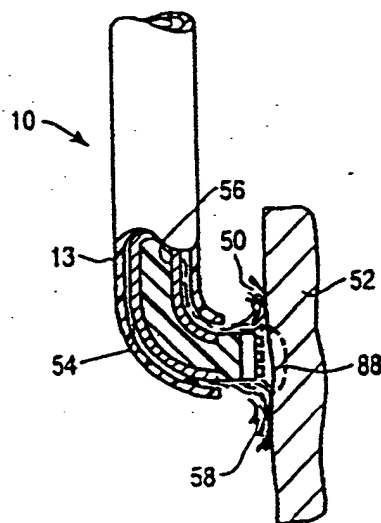


FIG. 11

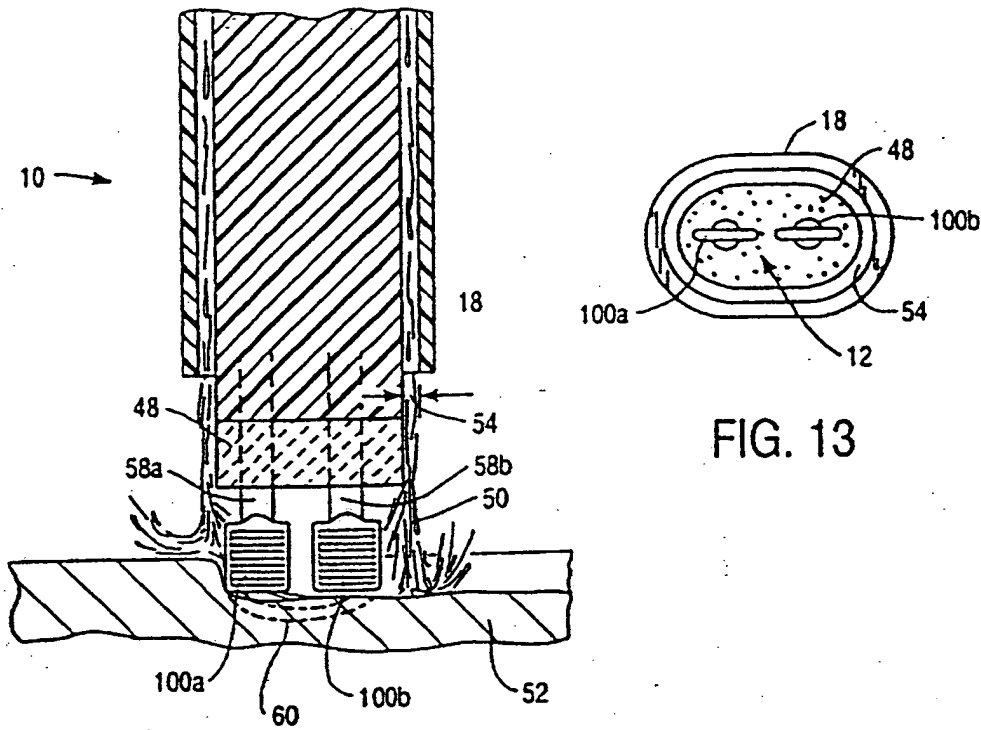


FIG. 13

FIG. 12

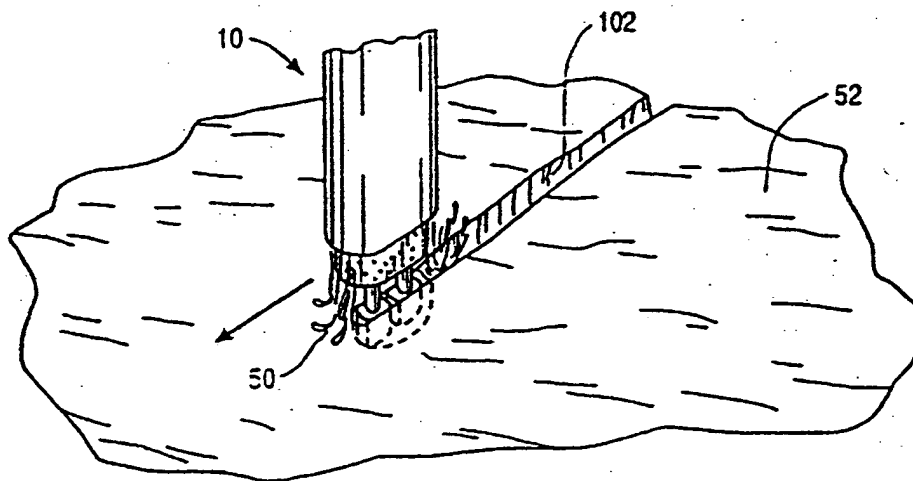


FIG. 14

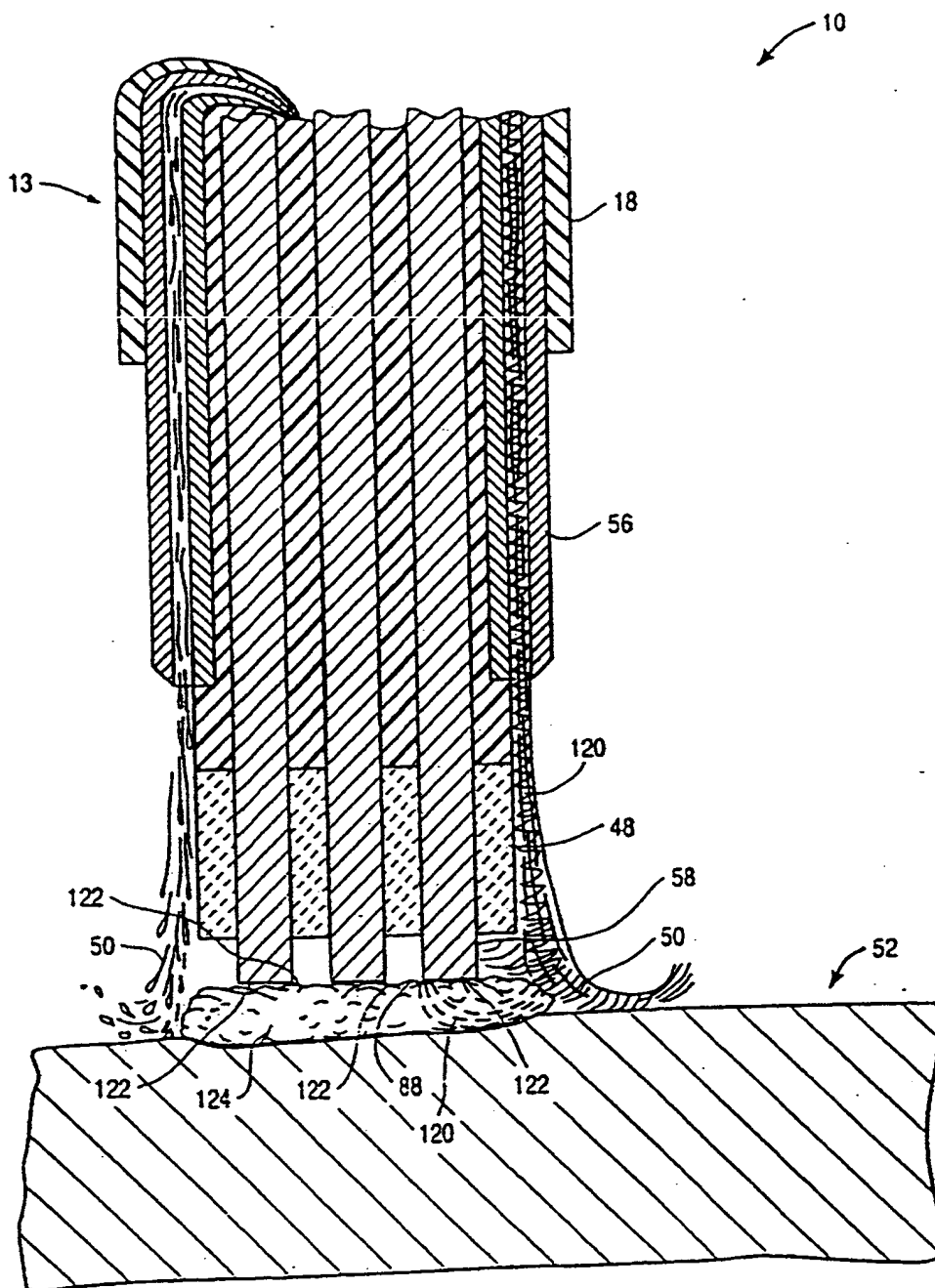


FIG. 15

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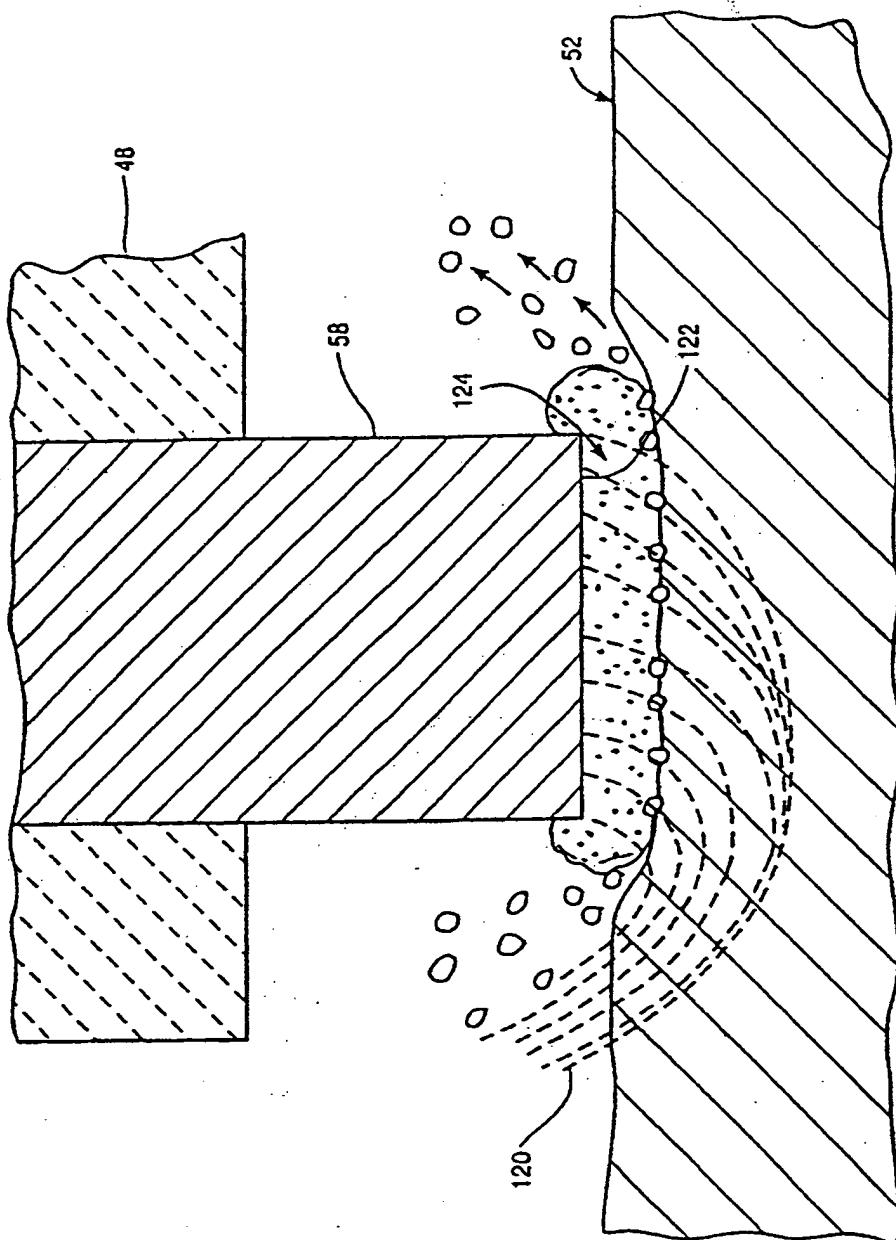
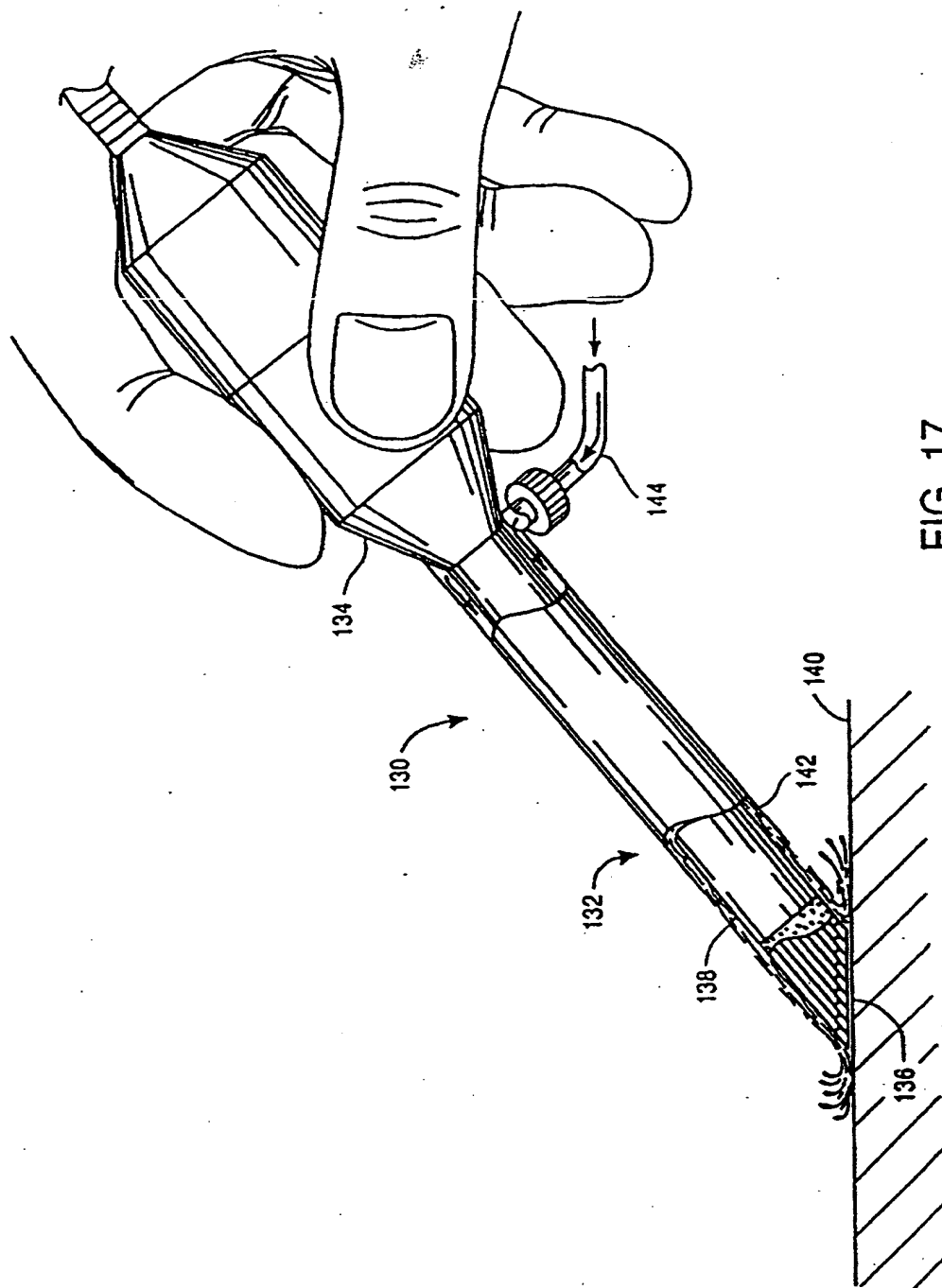


FIG. 16



A466.14

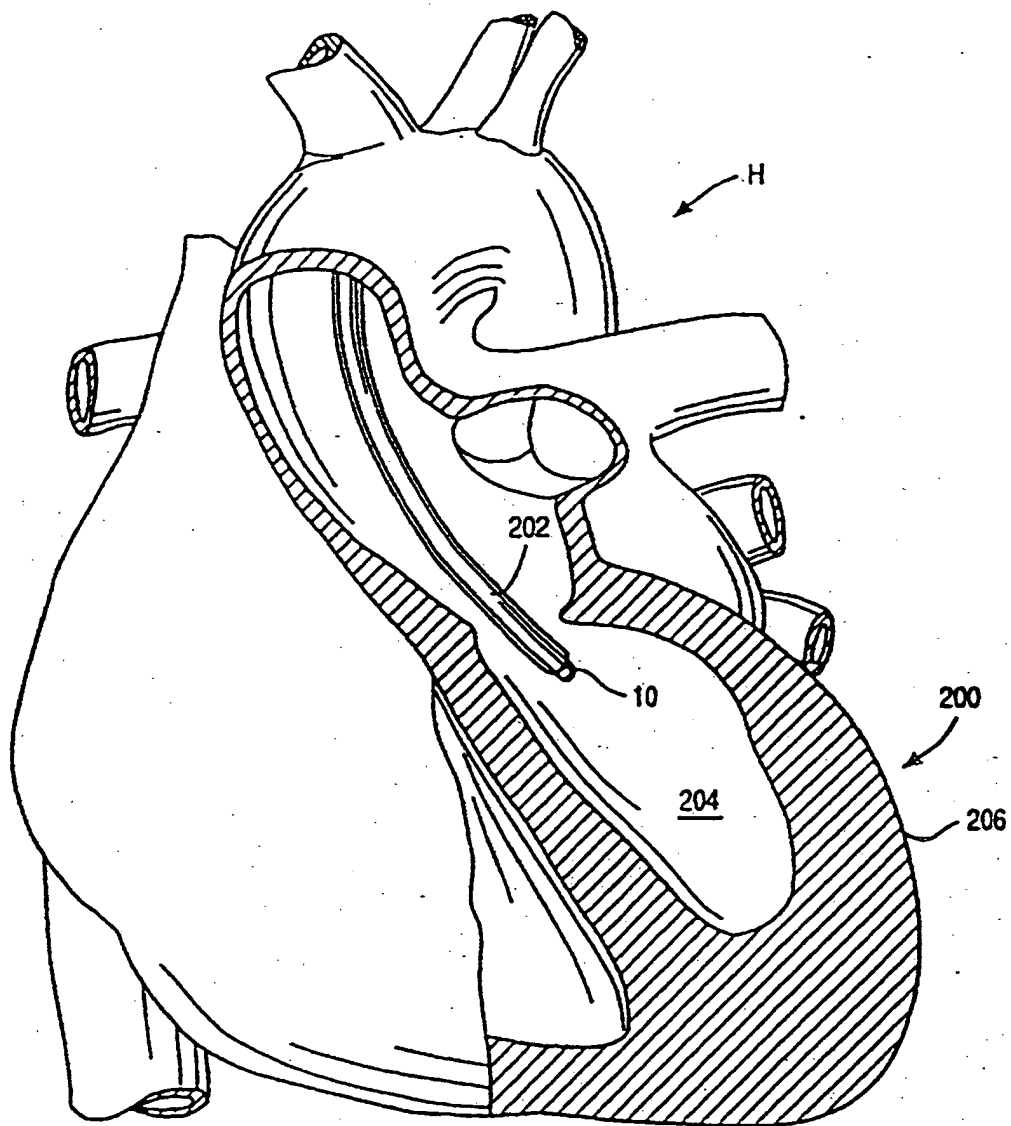


FIG. 18

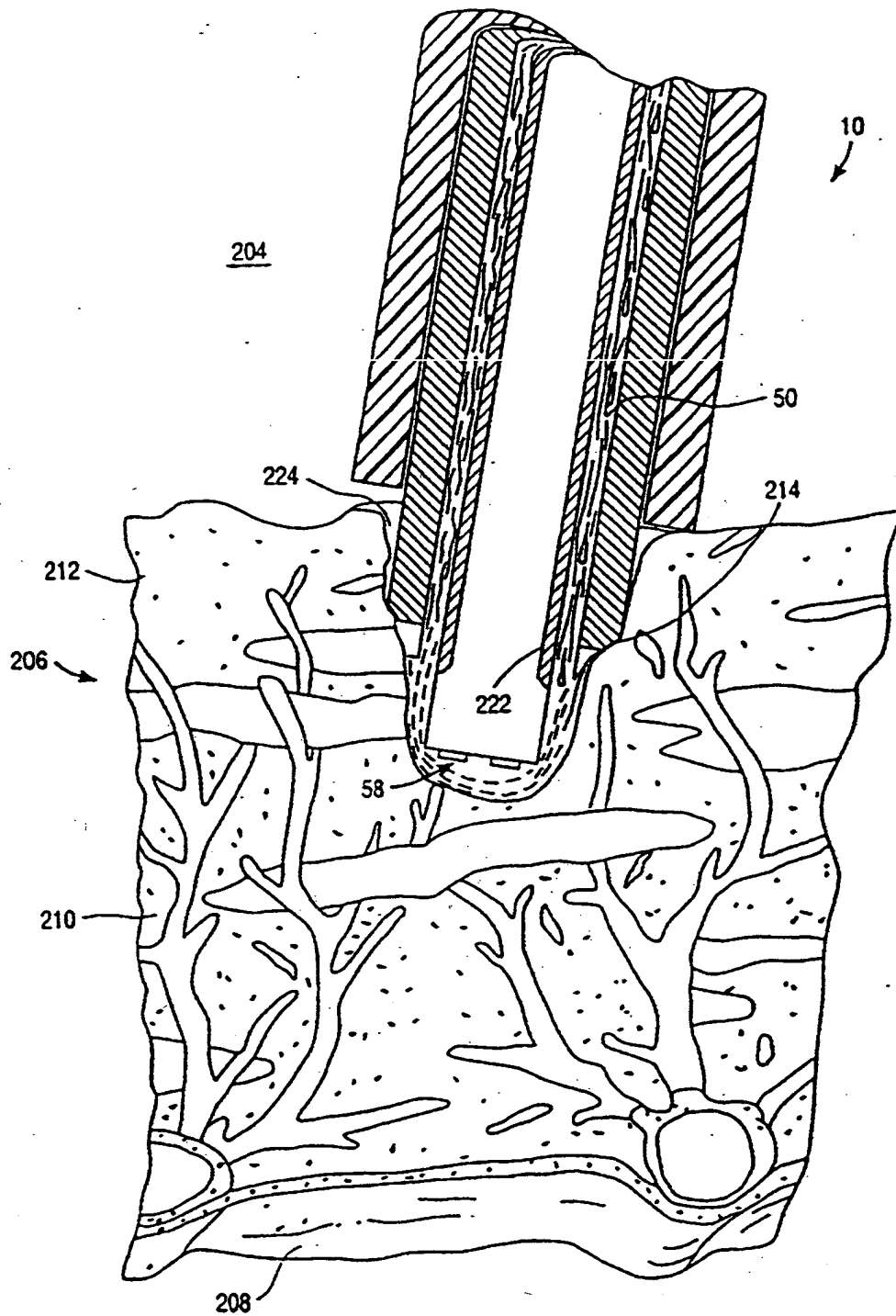


FIG. 19

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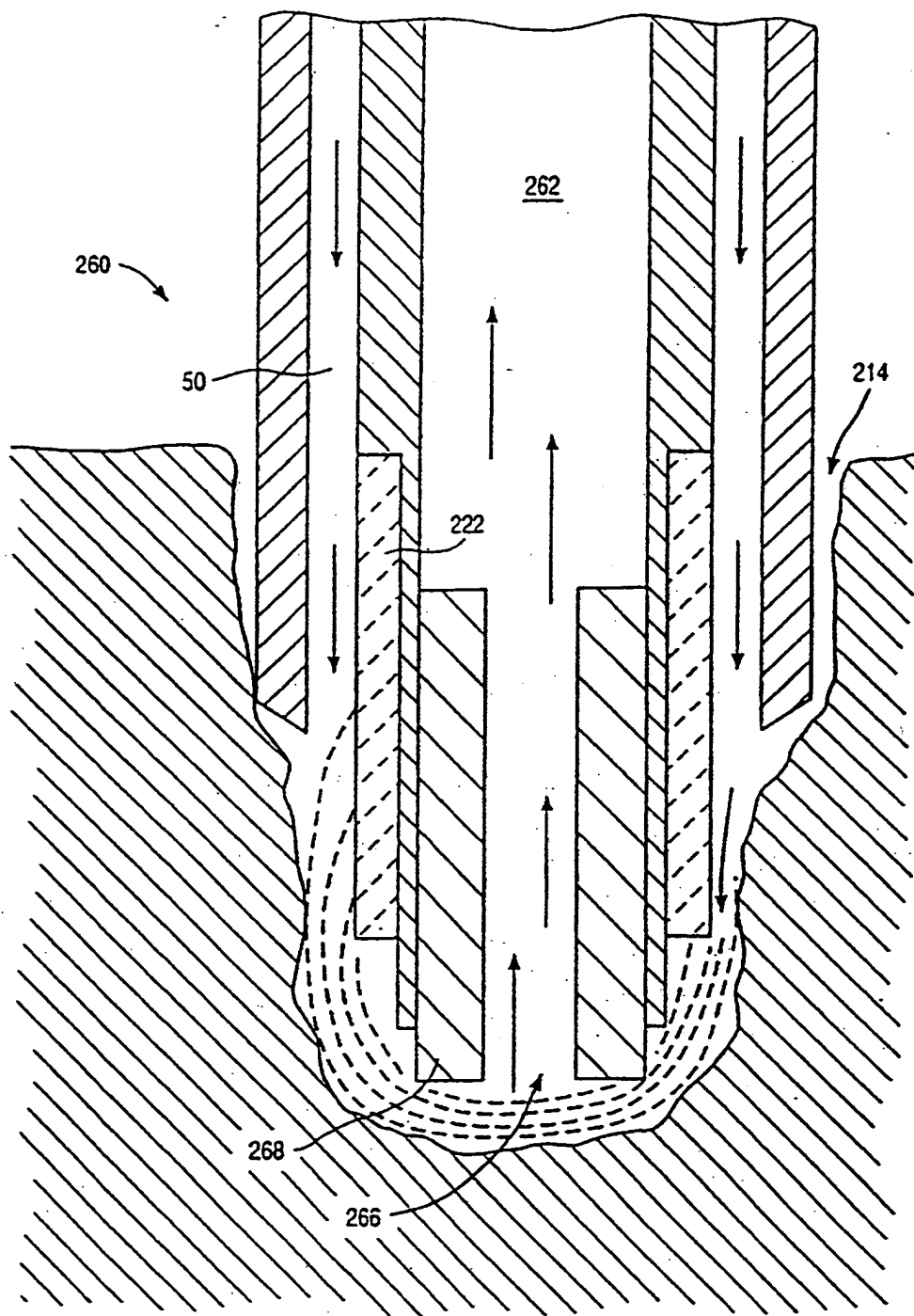


FIG. 20

A466.17

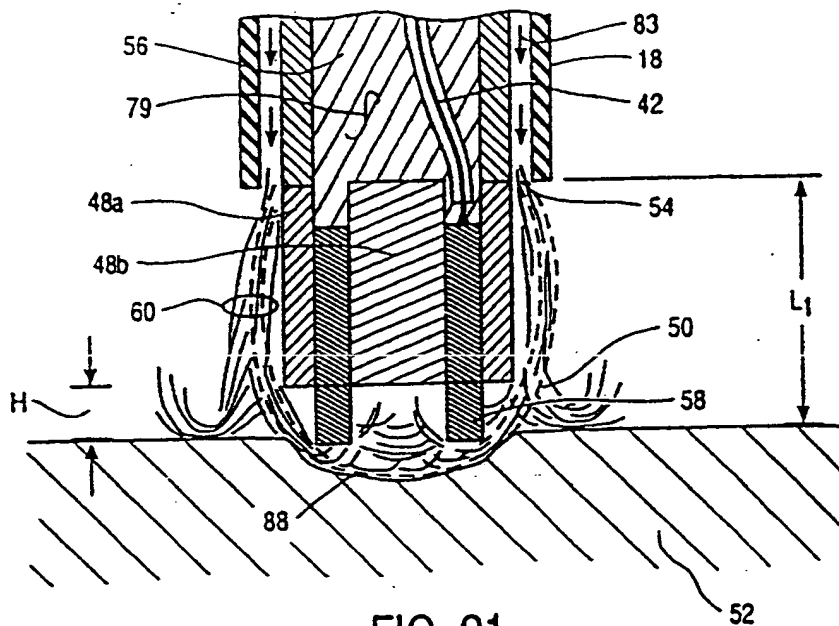


FIG. 21

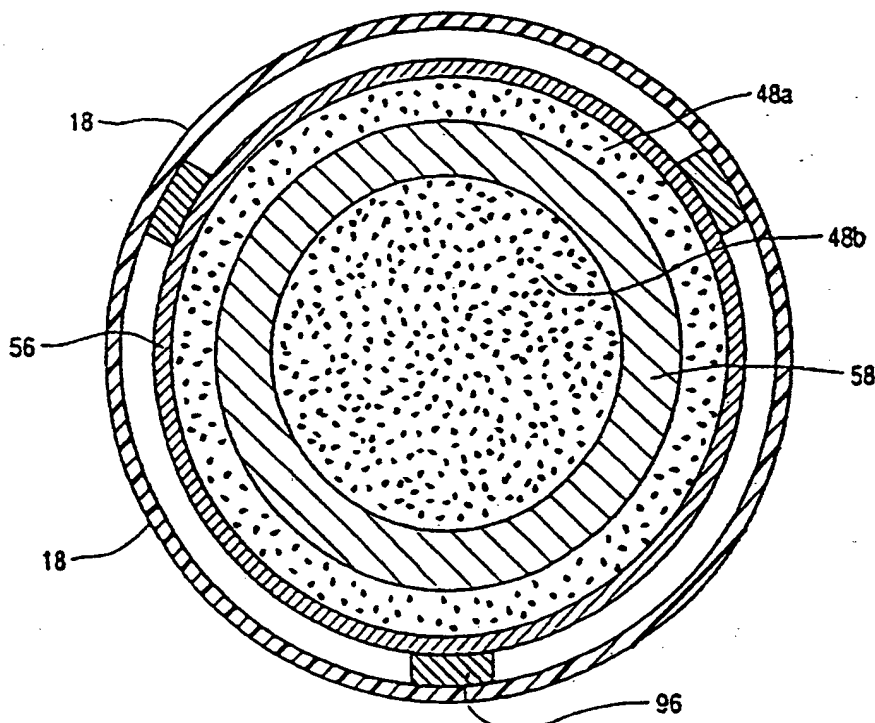


FIG. 22

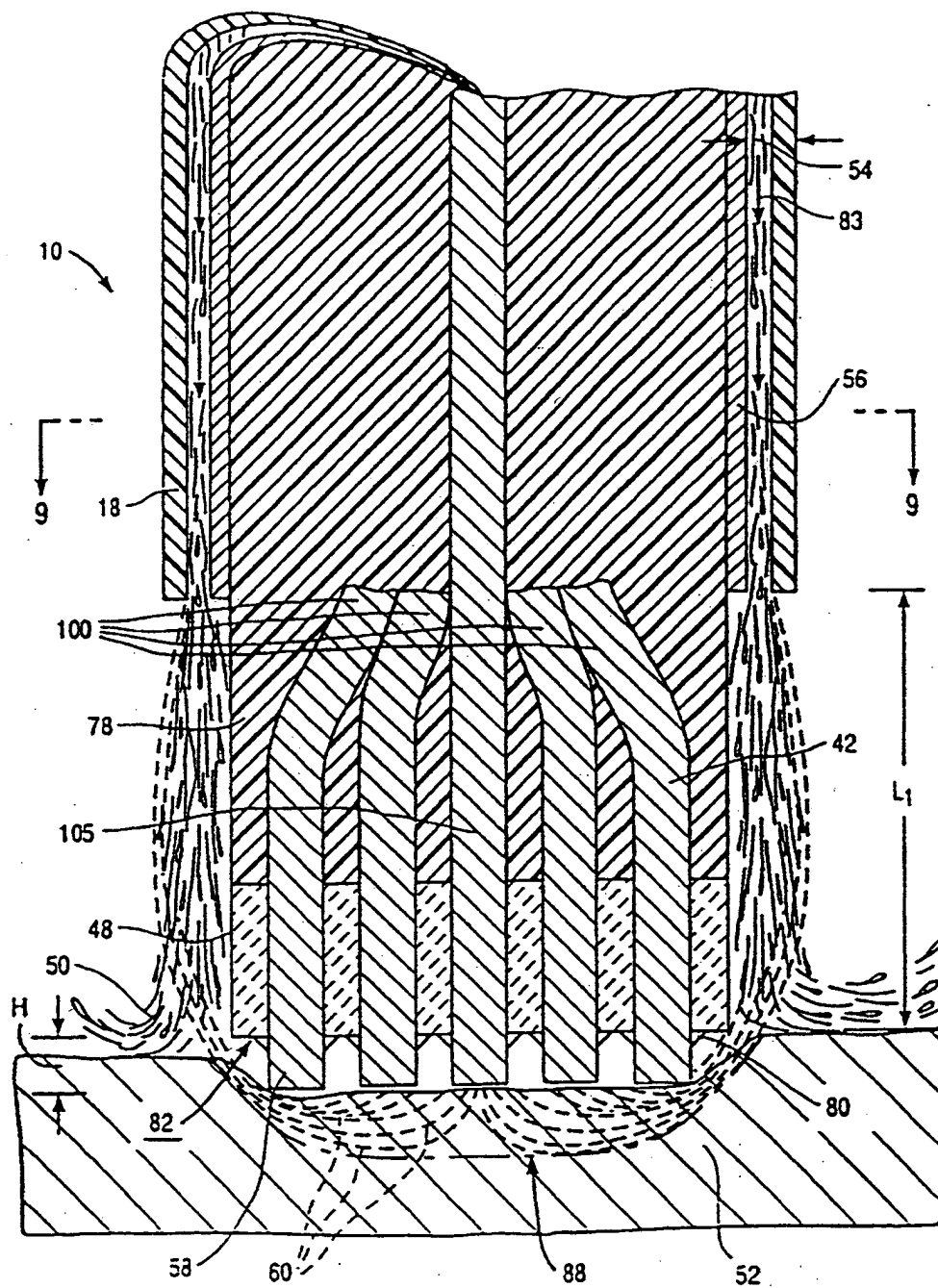


FIG. 23

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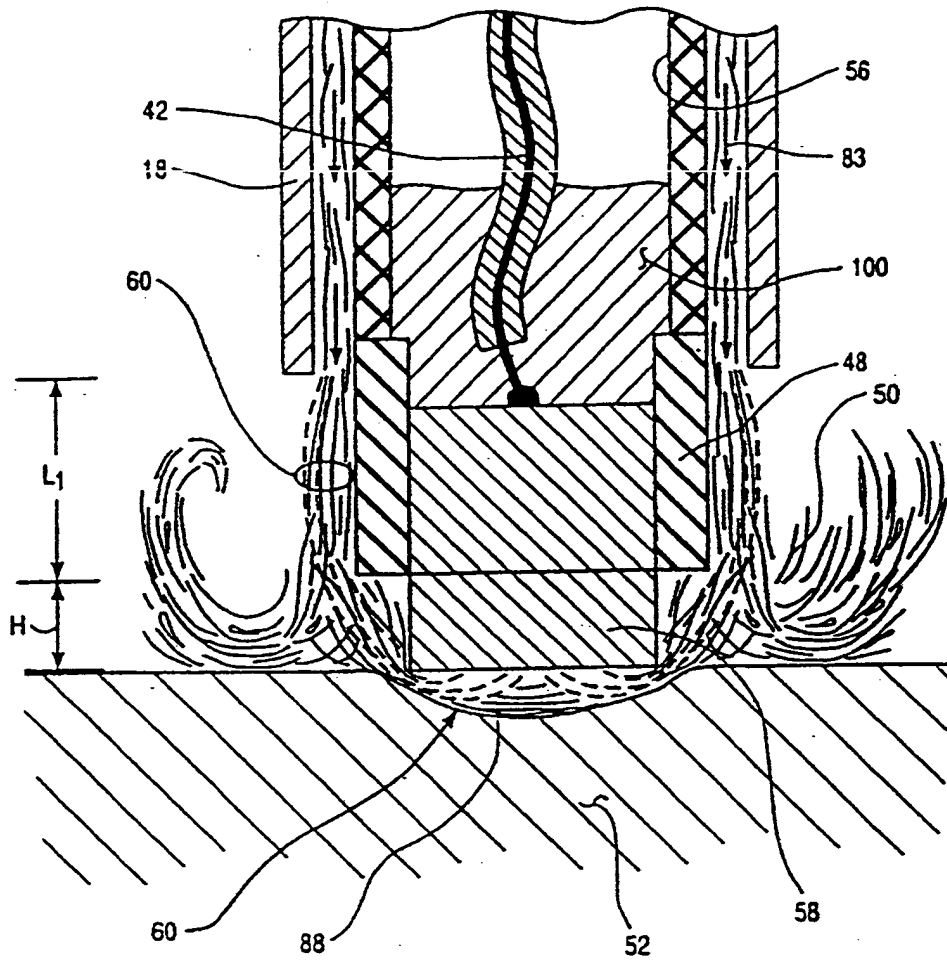


FIG. 24

A466.20

SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE TREATMENT IN CONDUCTIVE FLUID

The present invention is a division of application Ser. No. 08/795,686, filed Feb. 5, 1997, now U.S. Pat. No. 5,871,469, which is a division of application Ser. No. 08/561,958, filed Nov. 22, 1995, now U.S. Pat. No. 5,697,882, which is a continuation-in-part of application Ser. No. 08/485,219, filed Jun. 7, 1995, now U.S. Pat. No. 5,697,281, which is a continuation-in-part of application Ser. No. 08/446,767 filed Jun. 2, 1995, now U.S. Pat. No. 5,697,909 which is a U.S. National Phase Filing of International Application No. PCT/US94/05168, filed May 10, 1994, which is a continuation-in-part of application Ser. No. 08/059,681, filed May 10, 1993, now abandoned, which is a continuation-in-part of application Ser. No. 07/958,977, filed Oct. 9, 1992, now U.S. Pat. No. 5,366,443, which is a continuation-in-part of application Ser. No. 07/817,575, filed Jan. 7, 1992, now abandoned, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically

exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as eximer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric ablation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO_2

lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracoscopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent to the treatment site.

2. Description of the Background Art

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1:242-246 and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,455, 5,423,803, 5,102,410, 5,282,797, 5,290,273, 5,304,170, 5,312,395, 5,336,217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316, 4,658,817, 5,389,096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as scar or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the target tissue by a suitable distance during the ablation

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process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigant flooded environments, such as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return electrode.

The active and return electrodes will preferably be configured such that, upon the application of a sufficient high-frequency voltage, a thin layer of the electrically conducting liquid is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of ionizable species within the vapor layer or region and the emission of photon and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with

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or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy flux.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of an another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmymocardial revascularization procedure;

FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmyocardial channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for canalizing or boring channels or holes through tissue, such as the ventricular wall during transmyocardial revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the canalization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Ser. No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by using isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance

characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum)

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltages differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from vapor layer and to the surface of the target tissue. This energy may be in the form of energetic photons

(e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The photon energy produces photoablation through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photoablation is a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric breakdown of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces areas which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or region into the tissue, thereby minimizing joulean heating in, and associated necrosis of, the tissue.

As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 10^{20} atoms/cm³, which corresponds to about 3×10^{-3} grams/cm³. Applicants also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 10^{20} atoms/cm³ for aqueous solutions), electron avalanche occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring the region ahead of the front, viz, heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the inducement of energetic electrons and photons. The electrical conductivity of the fluid (in units of millisiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to engage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes

having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and current that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900 volts.

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed laser duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art, the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to irreversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 μ H to 50,000 μ H, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating therein.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 11 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced-apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

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in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

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rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-5, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along fluid path 83

through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described above.

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or arc tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48a of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloys thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 108. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or crimp connection 100. In FIG. 24, an electrosurgical probe 10

comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photon and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensable gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentations, such as freckles, tattoos, age or liver spots, birth marks, malignant melanomas, and superficial lentigines in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodysplasia, e.g., skin angioloma, malignant tumor tissue, lumbago (i.e., tissue bulges extending from the vertebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an electrosurgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum lucidum and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmyocardial revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen enriched blood flowing into the ventricular cavity from the aorta to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electrosurgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electrosurgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 206, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

Electrically conducting liquid 50 is delivered through an annular lumen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58, preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiments, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 50 to flow over the tissue surface being canalized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 20 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 260 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an open distal end 266 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 266 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, the heartbeat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole) of the heart.

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and positioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional manners. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

What is claimed is:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:

positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;

positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and

applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

2. The method of claim 1 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

3. The method of claim 1 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.

4. The method of claim 1 further comprising delivering the electrically conductive fluid to the target site.

5. The method of claim 4 wherein the electrode terminal is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the electrode terminal.

6. The method of claim 5 wherein the return electrode is an outer tubular member defining an axial passage between the outer surface of the probe and the inner surface of the outer tubular member, the delivering step including directing the electrically conductive fluid through the axial passage to the distal end of the probe over the electrode terminal.

7. The method of claim 4 further including positioning a distal end of a fluid supply shaft adjacent the electrode terminal, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the electrode terminal.

8. The method of claim 4 wherein the electrode terminal is located on a distal end of a probe and the return electrode is an inner tubular member defining an axial lumen, the delivering step including directing electrically conductive fluid through the axial lumen to the distal end of the probe over the electrode terminal.

9. The method of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of an instrument shaft.

10. The method of claim 1 wherein the electrode terminal includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft.

11. The method of claim 1 wherein the electrically conductive fluid comprises isotonic saline.

12. The method of claim 1 including independently controlling current flow to the electrode terminal based on

electrical impedance between the electrode terminal and the return electrode.

13. The method of claim 1 wherein the return electrode is spaced from the electrode terminal such that when the electrode terminal is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the electrode terminal and the return electrode.

14. The method of claim 1, wherein the return electrode is located on a distal end of an instrument shaft, further comprising an insulating matrix on the instrument shaft between the return electrode and the electrode terminal, the insulating matrix comprising an inorganic material.

15. The method of claim 14 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

16. The method of claim 14 further comprising applying a sufficient voltage difference between the return electrode and the electrode terminal to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal.

17. The method of claim 1 further comprising measuring the temperature at the target site and limiting power delivery to the electrode terminal if the measured temperature exceeds a threshold value.

18. The method of claim 1 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

19. The method of claim 18 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

20. The method of claim 18 wherein at least a portion of the energy is in the form of energetic electrons.

21. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

22. The method of claim 1 further comprising generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:

- contacting an active electrode with the body structure in the presence of an electrically conductive fluid;
- spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and
- applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.

24. The method of claim 23 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

25. The method of claim 23 wherein at least a portion of the electric current passes through the body structure.

26. The method of claim 23 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path between the active electrode and the return electrode.

27. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.

28. The method of claim 27 wherein the active electrode is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the active electrode.

29. The method of claim 27 further including positioning a distal end of a fluid supply shaft adjacent the active electrode, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the active electrode.

30. The method of claim 23 wherein the active electrode comprises a single active electrode disposed near the distal end of an instrument shaft.

31. The method of claim 23 wherein the active electrode includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft.

32. The method of claim 23 wherein the electrically conductive fluid comprises isotonic saline.

33. The method of claim 23 including independently controlling current flow to the active electrode based on electrical impedance between the active electrode and the return electrode.

34. The method of claim 23 wherein the return electrode is spaced from the active electrode such that when the active electrode is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the active electrode and the return electrode.

35. The method of claim 23, wherein the return electrode is located on a distal end of a probe, further comprising an insulating matrix at the distal tip of the probe between the return electrode and the active electrode, the insulating matrix comprising an inorganic material.

36. The method of claim 35 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

37. The method of claim 23 further comprising applying a sufficient voltage difference between the return electrode and the active electrode to effect the electrical breakdown of tissue in the immediate vicinity of the active electrode.

38. The method of claim 23 further comprising measuring the temperature at the target site and limiting power delivery to the active electrode if the measured temperature exceeds a threshold value.

39. The method of claim 23 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the active electrode and to induce the discharge of energy to the target site in contact with the vapor layer.

40. The method of claim 39 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

41. The method of claim 39 wherein at least a portion of the energy is in the form of energetic electrons.

42. The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

43. The method of claim 23 further comprising generating a voltage gradient between the active electrode and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

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BY HAND

The Honorable Sue L. Robinson
United States District Court
844 King Street
Wilmington, DE 19801

Re: ArthroCare Corp. v. Smith & Nephew;
C.A. No. 01-504 SLR

Dear Chief Judge Robinson:

[Redacted Content]

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The Honorable Sue L. Robinson
May 28, 2002
Page 2

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March 29, 2002

Perry Clark, Esq.
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Re: Arthrocare Suit - Delaware
USDC-D. Del. - C.A. No. 01-504-SLR

Dear Perry:

Pursuant to the discussion during the discovery conference, I have enclosed Smith & Nephew's supplemental noninfringement and invalidity responses, which are subject to and made without waiving Smith & Nephew's previous objections to ArthroCare's discovery requests. We reserve the right to revise these responses as discovery proceeds. In particular, we reserve the right to revise these responses after we have received meaningful discovery on ArthroCare's claim construction and infringement contentions, and after the Court has construed the asserted claims.

Smith & Nephew objects to ArthroCare's improper attempts to informally amend its infringement allegations. Our responses concern (1) the Dyonics Control RF System which is the only product alleged in ArthroCare's Complaint to infringe and (2) the asserted claims originally identified in Jared Bobrow's November 2, 2001 letter. We are not providing responses at this time for the additional claims listed in your March 15 letter since that was the first notice we received, just two weeks ago, that those claims were being asserted. We are in the process of preparing responses to those additional claims, however, and expect to have them to you within the next two weeks.

In addition, and in response to your letter of March 27, 2002, we are also not providing responses at this time for the Dyonics Electroblade Resector ("Electroblade") since it is not in the case. As you know, Electroblade was not accused in ArthroCare's Complaint. The only product ArthroCare accused in its Complaint was the Dyonics Control RF System. Further, ArthroCare failed to move to amend its Complaint as it is required to do under the Rules, and the deadline for amending pleadings in this case expired on March 8, 2002. Instead, ArthroCare merely stated in a letter a week later that "Electroblade is now among the accused products."

As you know, the accusation of infringement in a patent lawsuit is a formal step in the case that carries with it certain burdens to investigate under Rule 11. *Judin v. United*

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Perry Clark, Esq.
March 29, 2002
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States, 110 F.3d 780 (Fed. Cir. 1997); *Antonious v. Spalding & Everflo Companies, Inc.*, 275 F.3d 1066 (Fed. Cir. 2002). Indeed, in light of ArthroCare's argument during the discovery conference on March 5 that it needed discovery to determine whether Electroblade infringes, we were quite surprised that Electroblade was included in ArthroCare's infringement chart. Accordingly, we question whether ArthroCare can meet its burden under Rule 11 with respect to Electroblade.

Please let me know if you are in disagreement with any of the foregoing.

Very truly yours,



Keith Walter

Smith & Nephew's Supplemental Response Re Invalidity

In addition to its previous objections, and without waiving any of those objections, Smith & Nephew also objects to providing its invalidity contentions at this time, since ArthroCare has refused to provide any of its contentions with respect to construction of the claims of its patents. Accordingly, Smith & Nephew reserves the right to supplement, amend, or otherwise modify its invalidity contentions as the case proceeds, and particularly after ArthroCare provides its proposed claim construction and/or after the Court construes the claims of ArthroCare's patents.

Nevertheless, as of the present time, Smith & Nephew incorporates its previous responses by reference, and further responds as follows:

Certain of Smith & Nephew's invalidity contentions are based on invalidity under 35 U.S.C. § 102 and/or § 103 in view of certain prior art references. In the interest of brevity and convenience, rather than repeat the full names of those references in connection with each such contention, Smith & Nephew will instead refer to those references by number, in accordance with the following table:

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
1	08/16/33	US 2,056,377	F.C. Wappler	Electronic Instrument
2	05/00/69	Bio-Medical Engineering 206- 216	A.K. Dobbie	The Electrical Aspects of Surgical Diathermy
3	06/11/74	US 3,815,604	Conor C. O'Malley, Ralph M. Heintz, Sr.	Apparatus For Intraocular Surgery
4	08/13/74	US 3,828,780	Charles F. Morrison, Jr.	Combined Electrocoagulator- Suction Instrument
5	01/00/75	IEEE Transactions On Biomedical Engineering	William M. Honig	The Mechanism of Cutting in Electrosurgery

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
6	08/26/75	US 3,901,242	Karl Storz	Electric Surgical Instrument
7	11/18/75	US 3,920,021	Siegfried Hiltbrandt	Coagulating Devices
8	00/00/76	Acta Medicotechnica (Medizinal- Markt), Vol. 24, No. 4, 1976 129 - 134	E. Elsasser and E. Roos	Über ein Instrument zur leckstromfreien transurethralen Resektion (Concerning An Instrument for Transurethral resection without leakage of current)
9	02/24/76	US 3,939,839	Lawrence E. Curtiss	Resectoscope and Electrode Therefor
10	07/20/76	US 3,970,088	Charles F. Morrison	Electrosurgical Devices Having Sesquipolar Electrode Structures Incorporated Therein
11	01/07/77	2 313 949/ N 76 17587	Siegfried Hiltbrandt et Ludwig Bonnet	Boucle de sectionnement à une ou deux branches pour resectoscope
12	00/00/78	Gastroenterology, Vol. 74, No. 3, 527-534, 1978	J.R.A. Piercey, M.D., D.C. Auth, Ph.D., P.E., F.B. Silverstein, M.D., H.R. Willard, Ph.D., M.B. Dennis, D.V.M., D.M. Ellefson, B.S., D.M. Davis, M.S.E.E., R.L. Protell, M.D. and C.E. Rubin, M.D.	Electrosurgical Treatment of Experimental Bleeding Canine Gastric Ulcers: Development and testing of a computer control and a better electrode
13	02/21/78	US 4,074,718	Charles F. Morrison, Jr.	Electrosurgical Instrument
14	06/06/78	US 4,092,986	Max Schneiderman	Constant Output Electrosurgical Unit
15	09/26/78	US 4,116,198 and its file history	Eberhard Roos	Electro-Surgical Device
16	11/00/79	Digestive Diseases and Sciences, Vol. 24, No. 11, 845-848	M.B. Dennis, J. Peoples, R. Hulet, D.C. Auth, R.L. Protell, C.E. Rubin, and F.E. Silverstein	Evolution of Electrofulguration in Control of Bleeding of Experimental Gastric Ulcers

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
17	01/01/80	US 4,181,131	Hisao Ogiu	High Frequency Electrosurgical Instrument for Cutting Human Body Cavity Structures
18	01/22/80	US 4,184,492	Hans H. Meinke, Gerhard Flachenecker, Karl Fastenmeier, Friedrich Landstorfer, Heinz Lidenmeier	Safety Circuitry for High Frequency Cutting and Coagulating Devices
19	11/11/80	US 4,232,676	Andrew Herczog	Surgical Cutting Instrument
20	02/03/81	US 4,248,231	Andrew Herczog and James A. Murphy	Surgical Cutting Instrument
21	02/00/82	CRC Press, American Heart Journal, Vol. 117, 332-341	Kevin J. Barry, MS, Jonathan Kaplan, MD, Raymond J. Connolly, Ph.D, Paul Nardella, BS, Benjamin I. Lee, MD, Gary J. Becker, MD, Bruce F. Waller, MD, and Allan D. Callow, MD, Ph.D	The effect of radiofrequency- generated thermal energy on the mechanical and histologic characteristics of the arterial wall in vivo: Implications for radiofrequency angioplasty
22	04/27/82	US 4,326,529	James D. Doss and Richard L. Hutson	Corneal-Shaping Electrode
23	04/26/83	US 4,381,007	James D. Doss	Multipolar Corneal-Shaping Electrode with Flexible Removable Skirt
24	00/00/84	Gut, 25, 1424- 1431	C.P. Swan, IN Mills, E. Shemesh, Julia M. Dark, M.R. Lewin, J.S. Clifton, T.C. Northfield, P.B. Cotton, and P.R. Salmon	Which Electrode? A comparison of four endoscopic methods of electrocoagulation in experimental bleeding ulcers

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
25	00/00/85	Urological Research 13:99- 102	J.W.A. Ramsay, N.A. Shepherd, M. Butler, P.T. Gosling, R.A. Miller, D.M.A. Wallace, H.N. Whitfield	A Comparison of Bipolar and Monopolar Diathermy Probes in Experimental Animals
26	06/00/85	JACC Vol. 5, No. 6, 1382-6	Cornelius J. Slager, MSc, Catharina E. Essed, MD, Johan C.H. Schuurmakers, BSc, Nicolaas Bom, Ph.D, Patrick W. Serruys, MD, Geert T. Meester, MD, FACC	Vaporization of Atherosclerotic Plaques by Spark Erosion
27	10/22/85	US 4,548,207	Harry G. Reimels	Disposable Coagulator
28	05/27/86	US 4,590,934	Jerry L. Malis, Leonard I. Malis, Robert R. Acorcey, David Solt	Bipolar Cutter/Coagulator
29	00/00/87	Kardiologie, Kardiol. 76: Supp. 6, 67-71 (1987)	C.J. Slager, A.C. Phaff, C.E. Essed, J.C.H. Schuurmakers, N. Bom, V.A. Vandenbroucke, and P.W. Serruys	Spark Erosion of Arteriosclerotic Plaques
30	04/28/87	US 4,660,571	Stanley R. Hess, Terri Kovacs	Percutaneous Lead Having Radially Adjustable Electrode
31	06/23/87	US 4,674,499	David S.C. Pao	Coaxial Bipolar Probe
32	07/00/88	Valleylab Part Number 945 100 102 A	Valleylab, Inc.	Surgistat Service Manual
33	11/22/88	US 4,785,823	Philip E. Eggers, Robert F. Shaw	Methods And Apparatus For Performing In Vivo Blood Thermodilution Procedures
34	00/00/89	SPIE Vol. 1068 Catheter-based Sensing and Imaging Technology	Paul C. Nardella	Radio Frequency Energy and Impedance Feedback

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
35	00/00/89	The Organizing Committee of the 7 th World Congress on Endourology and ESWL Foundation for Advancement of International Science	Robert Tucker and Stefan Loening	A Bipolar Electrosurgical Turp Loop
36	02/21/89	US 4,805,616	David S.C. Pao	Bipolar Probes for Ophthalmic Surgery and Methods of Performing Anterior Capsulotomy
37	03/00/89	Journal of Urology Vol. 141, 662-665	Robert D. Tucker, Engene V. Kramolowsky, Eric Bedell and Charles E. Platz	A Comparison of Urologic Application of Bipolar Versus Monopolar Five French Electrosurgical Probes
38	04/00/89	JACC Vol. 13 No. 5, 1167-75	Benjamin I. Lee, MD, FACC, Gary J. Becker, MD, Bruce F. Waller, MD, FACC, Kevin J. Barry, MS, Raymond J. Connolly, Ph.D., Jonathan Kaplan, MD, Alan R. Shapiro, MS, Paul C. Nardella, BS	Thermal Compression and Molding of Atherosclerotic Vascular Tissue With Use of Radiofrequency Energy: Implications for Radiofrequency Balloon Angioplasty
39	04/25/89	US 4,823,791	Frank D. D'Amelio, Dawn M. DeLemos, Dominick G. Esposito, Michelle D. Maxfield, Claude E. Petruzzi, Robert H. Quint	Electrosurgical Probe Apparatus
40	05/23/89	US 4,832,048	Donald Cohen	Suction Ablation Catheter
41	00/00/90	Urological Research 18:291- 294	R.D. Tucker, E.V. Kramolowsky, and C.E. Platz	In vivo effect of 5 French bipolar and monopolar electrosurgical probes on the porcine bladder

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
42	02/00/90	Journal of Urology Vol. 143, 275-277	Eugene V. Kramolowsky and Robert D. Tucker	Use of 5P Bipolar Electrosurgical Probe in Endoscopic Urological Procedures
43	04/05/90	WO 90/03152	John Considine, John Collin	Electro-surgical Apparatus for Removing Tumours from Hollow Organs of the Body
44	05/01/90	US 4,920,978	David P. Colvin	Method and Apparatus for the Endoscopic Treatment of Deep Tumors Using RF Hyperthermia
45	06/05/90	US 4,931,047	Alan Broadwin, Charles Vassallo, Joseph N. Logan, Robert W. Hornlein	Method and Apparatus For Providing Enhanced Tissue Fragmentation And/Or Hemostasis
46	06/26/90	US 4,936,281	Peter Stasz	Ultrasonically Enhanced RF Ablation Catheter
47	10/30/90	US 4,966,597	Eric R. Cosman	Thermometric Cardiac Tissue Ablation Electrode with Ultra- Sensitive Temperature Detection
48	12/11/90	US 4,976,711	David J. Parms, Mark A. Rydell, Peter Stasz	Ablation Catheter With Selectively Deployable Electrodes
49	12/25/90	US 4,979,948	Leslie A. Geddes, Marvin H. Hinds, Joe D. Bourland, William D. Voorhes	Method and Apparatus for Thermally Destroying A Layer of An Organ
50	03/21/91	DE 3930451 A1	Ellen Hoffmann, Gerhard, Steinbeck, Rudi Mattnuller	Vorrichtung für die Hochfrequenzkoagulation von biologischem Gewebe
51	04/16/91	US 5,007,908	Mark A. Rydell	Electrosurgical Instrument Having Needle Cutting Electrode And Spot-Coag Electrode
52	04/23/91	US 5,009,656	Harry G. Reimels	Bipolar Electrosurgical Instrument
53	07/30/91	US 5,035,696	Mark A. Rydell	Electrosurgical Instrument for Conducting Endoscopic Retrograde Sphincterotomy

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
54	09/00/91	Journal of Urology Vol. 146, 669	Eugene V. Kramolowsky and Robert D. Tucker	The Urological Application of Electrosurgery
55	09/10/91	US 5,047,026	Mark A. Rydell	Electrosurgical Implement For Tunneling Through Tissue
56	09/10/91	US 5,047,027	Mark A. Rydell	Tumor Resector
57	10/07/91	Bipolar Laparoscopic Cholecystectomy Lecture	Dr. Olsen	Bipolar Laparoscopic Cholecystectomy
58	01/14/92	US 5,080,660	Terrence J. Bucina	Electrosurgical Electrode
59	01/28/92	US 5,084,044	Robert H. Quint	Apparatus for Endometrial Ablation and Method of Using Same
60	02/04/92	US 5,085,659	Mark A. Rydell	Biopsy Device With Bipolar Coagulation Capability
61	02/18/92	US 5,088,997	Louis Delahuerge, Robert B. Stoddard, Michael S. Klicek	Gas Coagulation Device
62	03/24/92	US 5,098,431	Mark A. Rydell	RF Ablation Catheter
63	04/28/92	US 5,108,391	Gerhard Flachenecker, Karl Fastermeier, Heinz Lindenmeier	High-Frequency Generator For Tissue Cutting And For Coagulating In High- Frequency Surgery
64	05/12/92	US 5,112,330	Shimichi Nishigaki, Shiro Bito	Resectoscope Apparatus
65	06/16/92	US 5,122,138	Kim H. Manwaring	Tissue Vaporizing Accessory and Method for an Endoscope
66	12/01/92	US 5,167,659	Naoki Ohtomo; Shizuo Ninomiya	Blood Coagulating Apparatus
67	12/15/92	US 5,171,311	Mark A. Rydell, David J. Parins, Steven W. Berbow	Percutaneous Laparoscopic Cholecystectomy Instrument
68	03/30/93	US 5,197,963	David J. Parins	Electrosurgical Instrument with Extendable Sheath for Irrigation and Aspiration
69	05/04/93	US 5,207,675	Jerome Canady	Surgical Coagulation Device

#	Issue/ Pub'n Date	Patent Number/ Publication	Inventor/Author	Title
70	06/08/93	US 5,217,459	William Kamerting	Method and Instrument for Performing Eye Surgery
71	04/26/94	US 5,306,238	Richard P. Fleckner	Laparoscopic Electrosurgical Pencil
72	06/13/95	US 5,423,882	Warren M. Jackman, Wilton W. Webster, Jr.	Catheter Having Electrode With Annular Recess and Method of Using Same
73	10/03/95	US 5,454,809	Michael Janssen	Electrosurgical Catheter And Method For Removing Artherosclerotic Plaque By Radio Frequency Sparking

1. U.S. Patent No. 5,697,536 ("the '536 patent")

A. Claim 45

Smith & Nephew contends that claim 45 of the '536 patent is anticipated by at least each of the following references: 3, 8, 12, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 31, 33, 35, 36, 37, 38, 41, 42, 43, 45, 46, 48, 49, 51, 52, 53, 54, 57, 61, 63, 65, 66, 67, 69, 70, 71.

Smith & Nephew also contends that claim 45 of the '536 patent would have been obvious to one of ordinary skill in the art at the time of the invention in view of at least each of the following combinations of references, which Smith & Nephew contends would have been combined for at least the following reasons:

Combination	Motivation to Combine
Any one or more of 1, 4, 5, 6, 7, 9, 10, 11, 13, 16, 17, 20, 30, 33, 39, 40, 44, 50, 55, 56, 58, 60, 61, 62, 64, 68, 69, 71, 72, 73 with any one or more of 35, 54, 57.	Each reference is directed to the same problem - applying electrical energy to a target site on a patient's body structure.
Any one or more of 1, 4, 5, 6, 7, 9, 10, 11, 13, 16, 17, 20, 30, 33, 39, 40, 44, 50, 55, 56, 58, 60, 61, 62, 64, 68, 69, 71, 72, 73 with any other one or more of the anticipating references listed above.	Each reference is directed to the same problem - applying electrical energy to a target site on a patient's body structure.

Combination	Motivation to Combine
Any one or more of 35, 54, 57 with 59.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.
Any one or more of 35, 54, 57 with any other one or more of the anticipating references listed above.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.
Any one or more of 2, 34, 47 with any one or more of the anticipating references listed above.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.
59 with any one or more of the anticipating references listed above.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.

2. U.S. Patent No. 5,697,882 ("the 882 patent")

A. Claim 1

Smith & Nephew contends that claim 1 of the '882 patent is anticipated by at least each of the following references: 2, 3, 5, 8, 15, 16, 18, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 34, 35, 36, 37, 38, 42, 45, 46, 48, 49, 51, 52, 53, 54, 55, 57, 61, 62, 63, 65, 66, 67, 68, 71, 73.

Smith & Nephew also contends that claim 1 of the '882 patent would have been obvious to one of ordinary skill in the art at the time of the invention in view of at least each of the following combinations of references, which Smith & Nephew contends would have been combined for at least the following reasons:

Combination	Motivation to Combine
Any one or more of 1, 6, 7, 9, 11, 17, 30, 39, 40, 44, 47, 50, 55, 56, 58, 61, 62, 64, 68, 69, 71, 73 with any other one or more of the anticipating references listed above.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.

Combination	Motivation to Combine
Any one or more of 1, 6, 7, 9, 11, 17, 30, 39, 40, 44, 47, 50, 55, 56, 58, 61, 62, 64, 68, 69, 71, 73 with any one or more of 2, 3, 4, 12, 16, 18, 21, 22, 23, 24, 25, 27, 28, 31, 33, 34, 35, 36, 37, 41, 42, 43, 45, 46, 48, 49, 51, 53, 54, 57, 60, 63, 66, 67, 70, 72 and with any one or more of 10, 13.	Each reference is directed to the same problem - applying electrical energy to a target site on a patient's body structure.
Any one or more of 2, 3, 4, 12, 16, 18, 21, 22, 23, 24, 25, 27, 28, 31, 33, 34, 35, 36, 37, 41, 42, 43, 45, 46, 48, 49, 51, 53, 54, 57, 60, 63, 66, 67, 70, 72 with any other one or more of the anticipating references listed above.	Each reference is directed to the same problem - applying electrical energy to a target site on a patient's body structure.
Any one or more of 2, 3, 4, 12, 16, 18, 21, 22, 23, 24, 25, 27, 28, 31, 33, 34, 35, 36, 37, 41, 42, 43, 45, 46, 48, 49, 51, 53, 54, 57, 60, 63, 66, 67, 70, 72 with any one or more of 10, 13.	Each reference is directed to the same problem - applying electrical energy to a target site on a patient's body structure.
Any one or more of 10, 13 with any other one or more of the anticipating references listed above.	Each reference is directed to the same problem - applying electrical energy to a target site on a patient's body structure.

Smith & Nephew further contends that claim 1 of the '882 patent is also invalid as indefinite under 35 U.S.C. § 112 ¶ 2.

B. Claim 26

Smith & Nephew contends that claim 26 of the '882 patent is anticipated by at least each of the following references: 2, 5, 23, 26, 29, 61, 63.

Smith & Nephew also contends that claim 26 of the '882 patent would have been obvious to one of ordinary skill in the art at the time of the invention in view of at least each of the following combinations of references, which Smith & Nephew contends would have been combined for at least the following reasons:

Combination	Motivation to Combine
Any one or more of 1, 6, 7, 10, 11, 13, 17, 30, 39, 40, 44, 47, 50, 55, 56, 58, 62, 64, 68, 69, 71, 73 with any one or more of 3, 4, 8, 12, 15, 16, 18, 21, 22, 23, 24, 25, 27, 28, 31, 33, 34, 35, 36, 37, 38, 41, 42, 43, 45, 46, 48, 49, 51, 52, 53, 54, 57, 60, 65, 66, 67, 70, 72 and with any one or more of 9, 14, 32, 61.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.
Any one or more of 1, 6, 7, 10, 11, 13, 17, 30, 39, 40, 44, 47, 50, 55, 56, 58, 62, 64, 68, 69, 71, 73 with any one or more of the anticipating references listed above.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.
Any one or more of 3, 4, 8, 12, 15, 16, 18, 21, 22, 24, 25, 27, 28, 31, 33, 34, 35, 36, 37, 38, 41, 42, 43, 45, 46, 48, 49, 51, 52, 53, 54, 57, 60, 65, 66, 67, 70, 72 with any one or more of 9, 14, 32, 61.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.
Any one or more of 3, 4, 8, 12, 15, 16, 18, 21, 22, 24, 25, 27, 28, 31, 33, 34, 35, 36, 37, 38, 41, 42, 43, 45, 46, 48, 49, 51, 52, 53, 54, 57, 60, 65, 66, 67, 70, 72 with any one or more of the anticipating references listed above.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.
Any one or more of 9, 14, 32, 61 with any one or more of the anticipating references listed above.	Each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure.

Smith & Nephew further contends that claim 26 of the '882 patent is also invalid as indefinite under 35 U.S.C. § 112 ¶ 2.

C. Claim 28

Smith & Nephew contends that claim 28 of the '882 patent is anticipated by at least each of the following references: 8, 15, 21, 26, 29, 41, 42, 45, 57.

Smith & Nephew also contends that claim 28 of the '882 patent would have been obvious to one of ordinary skill in the art at the time of the invention in view of at least each of the following combinations of references, which Smith & Nephew contends would have been combined for at least the following reasons:

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW'S SECOND MOTION FOR LEAVE TO AMEND ANSWER
AND COUNTERCLAIM

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DISTRICT OF DELAWARE

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

**[PROPOSED] ORDER GRANTING SMITH & NEPHEW, INC.'S
SECOND MOTION FOR LEAVE TO AMEND ANSWER AND
COUNTERCLAIM**

AND NOW, the Court, having considered the issues raised in Smith & Nephew's
Second Motion For Leave To Amend Answer And Counterclaim;

IT IS HEREBY ORDERED that the Motion is GRANTED and that the Amended
Answer and Counterclaim attached as Exhibit "A" to the Motion is deemed filed upon
entry of this Order.

SO ORDERED, this ____ day of _____, 2002.

United States District Judge

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of July, 2002, a true and correct copy of the within document was caused to be served on the attorneys of record at the following addresses as indicated:

BY HAND DELIVERY

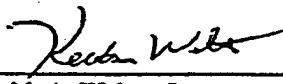
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BY FEDERAL EXPRESS

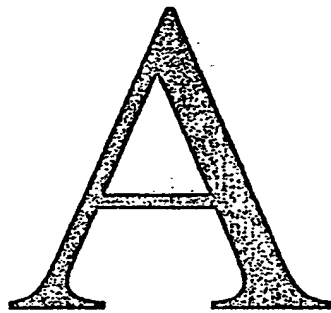
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

C.A. No. 01-504 SLR

SMITH & NEPHEW, INC.,

Counterclaim-Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim-Defendants.

AMENDED ANSWER AND COUNTERCLAIMS OF SMITH & NEPHEW, INC.

Defendant Smith & Nephew, Inc. ("Smith & Nephew"), answers the correspondingly numbered paragraphs of the complaint of plaintiff ArthroCare Corporation ("ArthroCare") as follows:

JURISDICTION AND VENUE

1. Smith & Nephew admits that ArthroCare's action purports to be one for alleged patent infringement arising under the patent laws of the United States, but Smith & Nephew denies that there has been any such infringement. Smith & Nephew admits that the Court has subject matter jurisdiction over this action. Smith & Nephew further admits that venue is technically proper.

2. Smith & Nephew is without sufficient knowledge or belief as to the truth of the allegations of Paragraph 2 and, on that basis, denies the allegations.

3. Admitted.

COUNT ONE

4. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

5. Smith & Nephew admits that what appears to be a copy of United States Patent No. 5,697,536 (the '536 patent'), entitled "System and Method for Electrosurgical Cutting and Ablation," is attached to the Complaint as Exhibit A. Smith & Nephew admits that the '536 patent issued on December 16, 1997 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 5 and, on that basis, denies them.

6. Denied.

7. Denied.

8. Denied.

COUNT TWO

9. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

10. Smith & Nephew admits that what appears to be a copy of United States Patent No. 5,697,882 ("the '882 patent"), entitled "System and Method for Electrosurgical Cutting and Ablation," is attached to the Complaint as Exhibit B. Smith

& Nephew admits that the '882 patent issued on December 16, 1997 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10 and, on that basis, denies them.

11. Denied.

12. Denied.

13. Denied.

COUNT THREE

14. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

15. Smith & Nephew admits that what appears to be a copy of United States Patent No. 6,224,592 ("the '592 patent"), entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," is attached to the Complaint as Exhibit C (referenced as Exhibit D in the Complaint). Smith & Nephew admits that the '592 patent issued on May 1, 2001 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15 and, on that basis, denies them.

16. Denied.

17. Denied.

18. Denied.

RELIEF REQUESTED BY ARTHROCARE

19. Smith & Nephew requests that the Court grant none of the relief requested by ArthroCare.

AFFIRMATIVE DEFENSES

**FIRST AFFIRMATIVE DEFENSE
(Non-Infringement)**

20. Smith & Nephew does not infringe and has not infringed, either directly, by inducing others to infringe, or by contributing to the infringement by others, any valid claim of the '536, '882 or '592 patents.

**SECOND AFFIRMATIVE DEFENSE
(Invalidity)**

21. The '536, '882 and '592 patents are each invalid because each fails to comply with the requirements of 35 U.S.C. § 101 et seq., including without limitation, Sections 102, 103 and 112.

**THIRD AFFIRMATIVE DEFENSE
(Misuse)**

22. The '536, '882, and '592 patents are each unenforceable for misuse, since, upon information and belief, ArthroCare filed this lawsuit knowing that each patent was invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

**FOURTH AFFIRMATIVE DEFENSE
(Unenforceability Based on Inequitable Conduct)**

23. The '592 patent is unenforceable based on inequitable conduct committed by ArthroCare, the applicants, and/or their attorneys during the prosecution in the United States Patent and Trademark Office ("USPTO") as set forth more fully in paragraphs 15-26 of Smith & Nephew's Counterclaim for a Declaratory Judgment of Non-Infringement,

Invalidity and Unenforceability.

FIFTH AFFIRMATIVE DEFENSE
(Unclean Hands)

24. ArthroCare is entitled to no relief since it comes into this Court with unclean hands since it has misused the '536, '882, and '592 patents and obtained the '592 patent through inequitable conduct.

SMITH & NEPHEW'S COUNTERCLAIMS
AGAINST ARTHROCARE

For its counterclaims against ArthroCare, Smith & Nephew alleges as follows:

JURISDICTION AND VENUE

1. These counterclaims are brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, Title 35 U.S.C., for a declaratory judgment that the '536, '882 and '592 patents are invalid and have not been infringed by any act of Smith & Nephew, and that the '592 patent is unenforceable.
2. ArthroCare has stated that it is a Delaware corporation with its principal place of business at 595 North Pastoria Avenue, Sunnyvale, California.
3. Smith & Nephew is a Delaware corporation with its principal place of business at 1450 Brooks Road, Memphis, Tennessee.
4. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338, 2201 and 2202. An actual and justiciable controversy exists between ArthroCare and Smith & Nephew as to the infringement and validity of the '536, '882 and '592 patents, and enforceability of the '592 patent, as evidenced by ArthroCare's Complaint in this action and Smith & Nephew's Answer to that Complaint, set forth above.

5. Venue is technically proper in this Court under 28 U.S.C. § 1391, and because ArthroCare has brought its Complaint for alleged infringement of the '536, '882 and '592 patents in this Court.

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT,
INVALIDITY AND UNENFORCEABILITY**

6. Smith & Nephew repeats and realleges the allegations of Paragraphs 1-5, above, as if fully set forth herein.

7. On December 16, 1997, the '536 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '536 patent.

8. On December 16, 1997, the '882 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '882 patent.

9. On May 1, 2001, the '592 patent, entitled "System and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '592 patent.

10. Smith & Nephew has not and does not infringe any valid claim of the '536, '882 or '592 patents.

11. The '536, '882 and '592 patents are each invalid because each fails to comply with the requirements of 35 U.S.C. § 101 *et seq.*, including without limitation, Sections 102, 103 and 112.

12. The '536, '882, and '592 patents are each unenforceable for misuse, since, upon information and belief, ArthroCare filed this lawsuit knowing that each patent was invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

13. ArthroCare is entitled to no relief since it comes into this Court with unclean hands since it has misused the '536, '882, and '592 patents and obtained the '592 patent through inequitable conduct.

14. The '592 patent is unenforceable based on inequitable conduct during prosecution of the '592 patent in the USPTO, as more particularly set forth below.

ArthroCare's Deceptive Activities In the Patent Office

15. On or about February 23, 1998, ArthroCare filed suit against Ethicon, Inc., *et al.*, in the U.S. District Court for the Northern District of California ("the California Court"), alleging infringement of four of its patents for electrosurgery devices and methods, including the '536 and '882 patents at issue in this action. That case was before Senior Judge William H. Orrick and was captioned *ArthroCare Corp. v. Ethicon, Inc.*, Civil Action No. 98-CV-609 ("the first ArthroCare case").

16. During the course of the first ArthroCare case, the California Court made extensive and detailed pretrial rulings, including a 33 page opinion dated on or about December 2, 1998 in which, among other things, it reviewed and interpreted 17 prior art references in the field of electrosurgery.

17. Significantly, in regard to one prior art reference, U.S. Patent No. 4,116,198 ("the Roos '198 reference"), there was a dispute between the parties as to whether the reference taught the use of an electrically conductive fluid in order to create a current flow between the active and return electrodes.

18. The California Court expressly found that the use of such a conductive fluid was explicitly described in claim 1 of the Roos '198 reference.

19. Upon information and belief, while the first ArthroCare case was pending, ArthroCare applied for the '592 patent, which then issued following the conclusion of that case.

20. During the prosecution of the application for the '592 patent, ArthroCare, the applicants and their attorney(s) were under a duty of candor and good faith in dealing with the USPTO, which included a duty to disclose to the USPTO all information material to patentability.

21. Upon information and belief, ArthroCare, the applicants and/or their attorney(s) violated their duty of candor and good faith and disclosure owed to the USPTO.

22. Upon information and belief, during the prosecution of the application for the '592 patent in the USPTO, neither ArthroCare, the applicants nor their attorney(s) complied with the Manual of Patent Examining Procedure § 2001.06(c) requiring the disclosure of material information arising from litigation concerning the subject matter for which a patent is being sought. For example, neither ArthroCare, the applicants nor their attorney(s) told the patent examiner that the Roos '198 reference disclosed the use of conductive fluid in claim 1 or that the California Court had specifically found that it had.

23. Instead, ArthroCare, the applicants and/or their attorney(s), submitted a supplemental information disclosure statement on or about October 25, 1999 in which they simply listed the California Court's December 2, 1998 opinion in a list of 84 pleadings that had been filed in the first ArthroCare case, but never submitted a copy of the opinion to the USPTO.

24. Further, during the prosecution of the application for the '592 patent, in an Office Action mailed on or about February 29, 2000, the patent examiner inferred that the Roos '198 device must inherently have used conductive fluid in order to work,

and as a result rejected certain claims of the application under 35 U.S.C. § 102(b) as being clearly anticipated by the Roos '198 reference.

25. In an Amendment filed in the USPTO on or about May 30, 2000, ArthroCare, the applicants and/or their attorney(s) responded to the patent examiner's rejection by making the misleading argument that Roos '198 device did not use conductive fluid. ArthroCare failed to inform the patent examiner of the California Court's decision that Claim 1 of the Roos '198 reference explicitly disclosed a conductive fluid. ArthroCare thus withheld material information and made affirmative misrepresentations concerning the Roos '198 patent.

26. Accordingly, the '592 patent is unenforceable due to inequitable conduct since, upon information and belief, ArthroCare, the applicants and/or their attorney(s) intentionally misrepresented and withheld material information from the USPTO with an intent to deceive the USPTO into issuing the '592 patent.

COUNTERCLAIM FOR ANTITRUST VIOLATIONS

27. Paragraphs 1-26 are incorporated herein by reference.

28. This counterclaim is for antitrust violations under 15 U.S.C. §1. This Court has jurisdiction over the subject matter of this counterclaim under the provisions of Federal Rules of Civil Procedure 13 and 19.

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PRAYER FOR RELIEF

WHEREFORE, Smith & Nephew prays that judgment be entered in its favor and against ArthroCare granting Smith & Nephew the following:

- A. That ArthroCare take nothing by this action;
- B. A declaration that Smith & Nephew does not infringe and has not infringed any claim of the '536 patent, the '882 patent or the '592 patent;
- C. A declaration that the '536, '882 and '592 patents are invalid;
- D. A declaration that the '536, '882 and '592 patents are unenforceable;
- E. An injunction enjoining ArthroCare, its officers, agents, servants, employees, and attorneys and those persons in active concert or participation with them who receive actual notice of this judgment, from directly or indirectly charging infringement, or instituting any action for infringement, of the '536 patent, '882 patent or '592 patent against Smith & Nephew or any of its customers, licensees, or suppliers;
- F. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285;

G. An award to Smith & Nephew of all its costs, expenses and attorneys' fees in this action;

H.

I. An award to Smith & Nephew of such other and further relief as the Court deems just and proper.

JURY DEMAND

Smith & Nephew demands trial by jury on all issues triable of right by a jury.

Dated: July 30, 2002

OF COUNSEL:

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SMITH & NEPHEW, INC.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

C.A. No. 01-504 SLR

SMITH & NEPHEW, INC.,

Counterclaim-Plaintiff,

v.

ARTHROCARE CORPORATION, AND

ETHICON, INC.,

Counterclaim-Defendants.

AMENDED ANSWER AND COUNTERCLAIMS OF SMITH & NEPHEW, INC.

Defendant Smith & Nephew, Inc. ("Smith & Nephew"), answers the correspondingly numbered paragraphs of the complaint of plaintiff ArthroCare Corporation ("ArthroCare") as follows:

JURISDICTION AND VENUE

1. Smith & Nephew admits that ArthroCare's action purports to be one for alleged patent infringement arising under the patent laws of the United States, but Smith & Nephew denies that there has been any such infringement. Smith & Nephew admits that the Court has subject matter jurisdiction over this action. Smith & Nephew further

admits that venue is technically proper, but denies that it is appropriate. Smith & Nephew has moved under 28 U.S.C. § 1404(a) for transfer of venue to the United States District Court for the Northern District of California.

2. Smith & Nephew is without sufficient knowledge or belief as to the truth of the allegations of Paragraph 2 and, on that basis, denies the allegations.

3. Admitted.

COUNT ONE

4. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

5. Smith & Nephew admits that what appears to be a copy of United States Patent No. 5,697,536 (the '536 patent'), entitled "System and Method for Electrosurgical Cutting and Ablation," is attached to the Complaint as Exhibit A. Smith & Nephew admits that the '536 patent issued on December 16, 1997 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 5 and, on that basis, denies them.

6. Denied.

7. Denied.

8. Denied.

COUNT TWO

9. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

10. Smith & Nephew admits that what appears to be a copy of United States Patent No. 5,697,882 ("the '882 patent"), entitled "System and Method for Electrosurgical Cutting and Ablation," is attached to the Complaint as Exhibit B. Smith & Nephew admits that the '882 patent issued on December 16, 1997 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10 and, on that basis, denies them.

11. Denied.

12. Denied.

13. Denied.

COUNT THREE

14. Smith & Nephew realleges and incorporates herein by reference the allegations and responses of Paragraphs 1 through 3, above.

15. Smith & Nephew admits that what appears to be a copy of United States Patent No. 6,224,592 ("the '592 patent"), entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," is attached to the Complaint as Exhibit C (referenced as Exhibit D in the Complaint). Smith & Nephew admits that the '592 patent issued on May 1, 2001 to Eggers, et al., but denies that such patent was duly and legally issued. Smith & Nephew is without information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15 and, on that basis, denies them.

16. Denied.

17. Denied.

18. Denied.

RELIEF REQUESTED BY ARTHROCARE

19. Smith & Nephew requests that the Court grant none of the relief requested by ArthroCare.

AFFIRMATIVE DEFENSES

**FIRST AFFIRMATIVE DEFENSE
(Non-Infringement)**

20. Smith & Nephew does not infringe and has not infringed, either directly, by inducing others to infringe, or by contributing to the infringement by others, any valid claim of the '536, '882 or '592 patents.

**SECOND AFFIRMATIVE DEFENSE
(Invalidity)**

21. The '536, '882 and '592 patents are each invalid because each fails to comply with the requirements of 35 U.S.C. § 101 et seq., including without limitation, Sections 102, 103 and 112.

**THIRD AFFIRMATIVE DEFENSE
(Misuse)**

22. The '536, '882, and '592 patents are each unenforceable for misuse, since, upon information and belief, ArthroCare filed this lawsuit knowing that each patent was invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

**FOURTH AFFIRMATIVE DEFENSE
(Unenforceability Based on Inequitable Conduct)**

23. The '592 patent is unenforceable based on inequitable conduct committed by ArthroCare, the applicants, and/or their attorneys during the prosecution in the United States Patent and Trademark Office ("USPTO") as set forth more fully in paragraphs 15-26 of Smith & Nephew's Counterclaim for a Declaratory Judgment of Non-Infringement,

Invalidity and Unenforceability.

FIFTH AFFIRMATIVE DEFENSE
(Unclean Hands)

24. - ArthroCare is entitled to no relief since it comes into this Court with unclean hands since it has misused the '536, '882, and '592 patents and obtained the '592 patent through inequitable conduct.

SMITH & NEPHEW'S COUNTERCLAIMS
AGAINST ARTHROCARE

For its counterclaims against ArthroCare, Smith & Nephew alleges as follows:

JURISDICTION AND VENUE

1. These counterclaims are brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, Title 35 U.S.C., for a declaratory judgment that the '536, '882 and '592 patents are invalid and have not been infringed by any act of Smith & Nephew, and that the '592 patent is unenforceable.

2. ArthroCare has stated that it is a Delaware corporation with its principal place of business at 595 North Pastoria Avenue, Sunnyvale, California.

3. Smith & Nephew is a Delaware corporation with its principal place of business at 1450 Brooks Road, Memphis, Tennessee.

4. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338, 2201 and 2202. An actual and justiciable controversy exists between ArthroCare and Smith & Nephew as to the infringement and validity of the '536, '882 and '592 patents, and enforceability of the '592 patent, as evidenced by ArthroCare's Complaint in this action and Smith & Nephew's Answer to that Complaint, set forth above.

5. Venue is technically proper in this Court under 28 U.S.C. § 1391, and because ArthroCare has brought its Complaint for alleged infringement of the '536, '882 and '592 patents in this Court. ~~Smith & Nephew has moved under 28 U.S.C. § 1404(a) for transfer of venue to the Northern District of California.~~

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT,
INVALIDITY AND UNENFORCEABILITY**

6. Smith & Nephew repeats and realleges the allegations of Paragraphs 1-5, above, as if fully set forth herein.

7. On December 16, 1997, the '536 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '536 patent.

8. On December 16, 1997, the '882 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '882 patent.

9. On May 1, 2001, the '592 patent, entitled "System and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," was issued by the USPTO in the name of Philip E. Eggers, *et al.* ArthroCare claims to be the owner of all right, title and interest in and to the '592 patent.

10. Smith & Nephew has not and does not infringe any valid claim of the '536, '882 or '592 patents.

11. The '536, '882 and '592 patents are each invalid because each fails to comply with the requirements of 35 U.S.C. § 101 et seq., including without limitation, Sections 102, 103 and 112.

12. The '536, '882, and '592 patents are each unenforceable for misuse, since, upon information and belief, ArthroCare filed this lawsuit knowing that each patent was invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

13. ArthroCare is entitled to no relief since it comes into this Court with unclean hands since it has misused the '536, '882, and '592 patents and obtained the '592 patent through inequitable conduct.

14. The '592 patent is unenforceable based on inequitable conduct during prosecution of the '592 patent in the USPTO, as more particularly set forth below.

ArthroCare's Deceptive Activities In the Patent Office

15. On or about February 23, 1998, ArthroCare filed suit against Ethicon, Inc., *et al.*, in the U.S. District Court for the Northern District of California ("the California Court"), alleging infringement of four of its patents for electrosurgery devices and methods, including the '536 and '882 patents at issue in this action. That case was before Senior Judge William H. Orrick and was captioned *ArthroCare Corp. v. Ethicon, Inc.*, Civil Action No. 98-CV-609 ("the first ArthroCare case").

16. During the course of the first ArthroCare case, the California Court made extensive and detailed pretrial rulings, including a 33 page opinion dated on or about December 2, 1998 in which, among other things, it reviewed and interpreted 17 prior art references in the field of electrosurgery.

17. Significantly, in regard to one prior art reference, U.S. Patent No. 4,116,198 ("the Roos '198 reference"), there was a dispute between the parties as to whether the reference taught the use of an electrically conductive fluid in order to create a current flow between the active and return electrodes.

18. The California Court expressly found that the use of such a conductive fluid was explicitly described in claim 1 of the Roos '198 reference.

19. Upon information and belief, while the first ArthroCare case was pending, ArthroCare applied for the '592 patent, which then issued following the conclusion of that case.

20. During the prosecution of the application for the '592 patent, ArthroCare, the applicants and their attorney(s) were under a duty of candor and good faith in dealing with the USPTO, which included a duty to disclose to the USPTO all information material to patentability.

21. Upon information and belief, ArthroCare, the applicants and/or their attorney(s) violated their duty of candor and good faith and disclosure owed to the USPTO.

22. Upon information and belief, during the prosecution of the application for the '592 patent in the USPTO, neither ArthroCare, the applicants nor their attorney(s) complied with the Manual of Patent Examining Procedure § 2001.06(c) requiring the disclosure of material information arising from litigation concerning the subject matter for which a patent is being sought. For example, neither ArthroCare, the applicants nor their attorney(s) told the patent examiner that the Roos '198 reference disclosed the use of conductive fluid in claim 1 or that the California Court had specifically found that it had.

23. Instead, ArthroCare, the applicants and/or their attorney(s), submitted a supplemental information disclosure statement on or about October 25, 1999 in which they simply listed the California Court's December 2, 1998 opinion in a list of 84 pleadings that had been filed in the first ArthroCare case, but never submitted a copy of the opinion to the USPTO.

24. Further, during the prosecution of the application for the '592 patent, in an Office Action mailed on or about February 29, 2000, the patent examiner inferred that the Roos '198 device must inherently have used conductive fluid in order to work.

and as a result rejected certain claims of the application under 35 U.S.C. § 102(b) as being clearly anticipated by the Roos '198 reference.

25. In an Amendment filed in the USPTO on or about May 30, 2000, ArthroCare, the applicants and/or their attorney(s) responded to the patent examiner's rejection by making the misleading argument that Roos '198 device did not use conductive fluid. ArthroCare failed to inform the patent examiner of the California Court's decision that Claim 1 of the Roos '198 reference explicitly disclosed a conductive fluid. ArthroCare thus withheld material information and made affirmative misrepresentations concerning the Roos '198 patent.

26. Accordingly, the '592 patent is unenforceable due to inequitable conduct since, upon information and belief, ArthroCare, the applicants and/or their attorney(s) intentionally misrepresented and withheld material information from the USPTO with an intent to deceive the USPTO into issuing the '592 patent.

COUNTERCLAIM FOR ANTITRUST VIOLATIONS

27. Paragraphs 1-26 are incorporated herein by reference.

28. This counterclaim is for antitrust violations under 15 U.S.C. §1. This Court has jurisdiction over the subject matter of this counterclaim under the provisions of Federal Rules of Civil Procedure 13 and 19.

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PRAYER FOR RELIEF

WHEREFORE, Smith & Nephew prays that judgment be entered in its favor and against ArthroCare granting Smith & Nephew the following:

- A. That ArthroCare take nothing by this action;
- B. A declaration that Smith & Nephew does not infringe and has not infringed any claim of the '536 patent, the '882 patent or the '592 patent;
- C. A declaration that the '536, '882 and '592 patents are invalid;
- D. A declaration that the '536, '882 and '592 patents are unenforceable;
- E. An injunction enjoining ArthroCare, its officers, agents, servants, employees, and attorneys and those persons in active concert or participation with them who receive actual notice of this judgment, from directly or indirectly charging infringement, or instituting any action for infringement, of the '536 patent, '882 patent or '592 patent against Smith & Nephew or any of its customers, licensees, or suppliers;
- F. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285;

G. An award to Smith & Nephew of all its costs, expenses and attorneys' fees in this action; and

H.

HI. An award to Smith & Nephew of such other and further relief as the Court deems just and proper.

JURY DEMAND

Smith & Nephew demands trial by jury on all issues triable of right by a jury.

Dated: September 13, 2001

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

CONFIDENTIAL INFORMATION
SUBJECT TO PROTECTIVE ORDER

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**OPENING BRIEF IN SUPPORT OF SMITH & NEPHEW'S SECOND
MOTION FOR LEAVE TO AMEND ANSWER AND COUNTERCLAIM**

Dated: July 30, 2002

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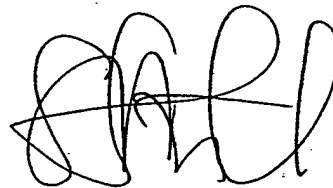
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